revised dangerous preparations directive (1999/45/EC) -- implications for petroleum products

Prepared by:

T. Clarke-Sturman
D. Coker
G. Ebbon
H. Terhell
T. Riley
J. Wennington

B. Dmytrasz (Technical Coordinator)

Brussels
December 2000

ABSTRACT

This report highlights and explains the significance of the changes regarding the classification and labelling of preparations introduced by this revision (1999/45/EEC) to the Dangerous Preparations Directive, including the classification and labelling of preparations for environmental endpoints, revised disclosure requirements, Safety Data Sheets and implications for distance selling.

KEYWORDS

Hazard, health, environmental, flammability, preparations, petroleum products, classification, packaging, labelling, dangerous preparations directive.

CONTENTS

1. INTRODUCTION

The purpose of this report is to highlight and explain the significance of the changes regarding the classification and labelling of preparations introduced by Directive 1999/45/EC [1] (the revised Dangerous Preparations Directive) which replaces the original Dangerous Preparations Directive 88/379/EEC [2]. This new Directive (see **Appendix 1**) requires Member States to adopt and publish laws, regulations and administrative provisions necessary to comply with the Directive before 30 July 2002.

This report examines Directive 1999/45/EC Article-by-Article, describes the changes and examines their impact in the context of petroleum products. Whilst a number of Articles are either not revised, or the revisions are of little significance to the oil industry, there are some major changes as outlined below.

1.1. ENVIRONMENTAL CLASSIFICATION

The major change is the introduction of the requirement for the first time for suppliers of finished products to evaluate preparations for environmental hazards and to classify and label them if appropriate. This brings with it the need for producers of additives and additive packages also to evaluate and classify and label, if necessary, their products for environmental effects. The report focuses in some detail on the procedures to be adopted for handling environmental classification.

The recommended environmental classifications for petroleum substances are given in CONCAWE report number 98/54 titled "Classification and labelling of petroleum substances according to the EU dangerous substances directive" and its subsequent updates.

1.2. GENERIC NAMES – DISCLOSURE REQUIREMENTS

Restrictions, and modified arrangements, are introduced for the use of generic names for disclosure of dangerous components. The disclosure requirements for preparations (both classified and unclassified) containing substances classified as sensitisers are made more stringent.

1.3. SAFETY DATA SHEETS (SDSs)

Article 14 extends the scope for the provision of Safety Data Sheets (SDSs), extending the right of professional users to request SDSs containing “proportionate” information for certain non-dangerous preparations. The implications of this, both in terms of what is meant by “proportionate” and for those companies already providing standard 16-section format SDSs for non-dangerous preparations, are not clear at the time of the publication of this report.

1.4. DISTANCE SELLING

The Dangerous Substances Directive [3] (DSD) has always contained an article requiring the provision of hazard advice before concluding a contract where the prospective purchaser does not have the opportunity to examine the label ("distance selling"). This has, however, not been considered of great significance since most products sold are preparations to which this provision did not hitherto apply. The extension of this requirement to preparations (formulated products) greatly increases the scope of products and trading regimes (e-commerce, mail/phone orders) covered by this provision.

1.5. IMPACT ON OTHER DIRECTIVES

Directive 1999/45/EEC provides for the repeal of a number of existing Directives, notably Directive 88/379/EEC and also calls for Annex VI [4,5,6,10] of the DSD to be updated.

2. EC DANGEROUS PREPARATIONS DIRECTIVE - THE MAIN PROVISIONS RELATING TO PETROLEUM PRODUCTS

2.1. ARTICLE 1 - OBJECTIVES AND SCOPE

The scope of the DPD has been expanded to include environmental classification and labelling criteria for preparations. In addition, for non-dangerous preparations containing a dangerous substance below the concentration threshold to trigger classification of the product as 'dangerous', suppliers will have to provide, on request, an SDS to industrial users if any dangerous substance is present at a level greater than 1% (w/w) for liquids and solids, or, greater than 0.2% (vol/vol) in the case of gaseous preparations.

The third major change in the new DPD is that from 2004 it will be extended to cover plant protection products, such as herbicides for agricultural and domestic use, which are currently classified and labelled under a different scheme.

The DPD does not apply to mixtures of substances in the form of waste.

2.2. ARTICLE 2 - DEFINITIONS

No definitions were included in the original DPD (88/379/EEC), which referred to the definitions in the DSD (67/548/EEC).

The following list of definitions are included in Directive 1999/45/EC, which are identical to the definitions for these items given in the 7th amendment [7] to the DSD.

Substances
Preparations
Polymer
Placing on the market
Scientific research and development
Process oriented research and development
EINECS

The definition of "notification" is not included in the new DPD as notification applies only to substances, not to preparations. Most petroleum streams are "complex substances", also known as UVCB's (Substances of Unknown or Variable composition, Complex reaction products & Biological materials), which are regulated as substances under the DSD. Most marketed petroleum products are blends including additives and are regulated as preparations under the DPD.

Definitions of categories of danger (Article 2.2) are now included in the DPD. They are identical to those in the DSD.

2.3. ARTICLE 3 - DETERMINATION OF DANGEROUS PROPERTIES OF PREPARATIONS

In addition to the evaluation of physico-chemical properties and the properties affecting health, there is now also a need to evaluate the environmental hazards of preparations.

All laboratory tests to be conducted shall be carried out on the preparation "as placed on the market". All dangerous substances present in a preparation have to be taken into consideration for this determination. This includes all components, impurities and additives if present in concentrations as shown in the following table.

Category of danger of the substance	Concentration to take into consideration for	
	gaseous preparations % vol/vol	other preparations % w/w
• Very toxic • Toxic • Carcinogenic category 1 or 2 • Mutagenic category 1 or 2 • Toxic for reproduction, category 1 or 2	≥0,02	≥0,1
• Corrosive	≥0,02	≥1
• Irritant • Harmful • Sensitising • Carcinogenic, category 3 • Mutagenic, category 3 • Toxic for reproduction, category 3	≥0,2	≥1
• Dangerous for the environment - N	not applicable	≥0,1
• Dangerous for the environment - ozone	≥0,1	≥0,1
• Dangerous for the environment	not applicable	≥1

2.4. ARTICLE 4 - GENERAL PRINCIPLES OF CLASSIFICATION AND LABELLING

This article outlines the general principles to be followed in classifying and labelling dangerous preparations. It indicates that health, environmental and physico-chemical classifications are based on the intrinsic hazardous properties of a preparation. The evaluation procedures and criteria to be applied are specified in Articles 5, 6 and 7 of Directive 1999/45/EC and also in Annex VI of the DSD.

2.5. ARTICLE 5 - EVALUATION OF THE HAZARDS DERIVING FROM PHYSICO-CHEMICAL PROPERTIES

Physico-chemical properties for classification are to be determined by methods in Annex V [5,8,9,10] of the DSD. There is no requirement that the testing of physico-chemical properties complies with Good Laboratory Practices (GLP's).

A derogation from testing to determine the explosive, oxidising, extremely flammable, highly flammable or flammable properties is provided in the following situation:

- none of the constituents possess such properties
- **and,** on the basis of the information available to the manufacturer, the preparation is unlikely to present hazards of this kind (as in the case of most formulated lubricants).

Physico-chemical properties for preparations placed on the market in the form of aerosol dispensers and which satisfy the provisions of Article 9a of the Aerosol Dispensers Directive (Directive 75/324/EEC [11] as last amended by Directive 94/1/EC [12]), do not have to be determined.

Consideration of information regarding the potential of a preparation to accumulate a static charge is not required by this Directive and there are no classification criteria for this property. CONCAWE, however, recommends that information on this potential hazard be provided in SDSs where applicable.

2.6. ARTICLE 6 - EVALUATION OF HEALTH HAZARDS

This Article, in conjunction with Articles 5 and 7, provides the procedures to be followed in evaluating the health, safety and environmental hazards, and hence classifications, of preparations. Article 6 deals with the evaluation of health hazards, which can be assessed either by a 'conventional' method, or, in certain cases, by testing the preparation using recognised test methods.

Application of a 'conventional' method provides a hazard classification of a preparation, based on the classifications of its components., Details of 'conventional' methods for the various health endpoints are included in Annex II, Parts A and B. It should be recognised however that, although testing of a preparation is permitted, Directive 1999/45/EC now places greater emphasis on using a 'conventional' method, by requiring that suppliers only undertake experimental studies where it can be demonstrated scientifically that the toxicological properties of the preparation cannot be determined correctly by other methods (see section 6.6)**.** Manufacturers/suppliers therefore need to consider this issue carefully and document the rationale for undertaking the test work.

The evaluation of the health hazards of a preparation will thus normally be undertaken using 'conventional' methods, technical details of which are now included in Annex II of Directive 1999/45/EC. These provide a systematic approach to the assessment of health hazard endpoints, using specified concentration limits, to trigger classification. The concentration limits to be applied when a preparation contains a single hazardous component are either specified in Annex I to Directive 67/548/EEC or subject to default limits [see tables in Annex II, Part B of Directive 1999/45/EC]. If a preparation contains more than one component with the same hazard, then for most health endpoints, it is necessary to apply a calculation to determine whether classification is necessary. The formulae to be applied are given in Annex II, Part A.

For classification purposes, where toxicological data are available for the preparation supplied, these data will normally take precedence over the classification outcome of a 'conventional' method. If information available suggests

however that the results of a 'conventional' method either under or over estimate the health hazards, or human data [e.g. epidemiology studies, scientifically valid case studies] indicate that health effects differ from those predicted, then these factors should be taken into account when classifying the preparation. An important exception to this is the evaluation of preparations for their carcinogenic, mutagenic or reproductive hazards which shall be based only on the 'conventional' method.

Key points from Article 6 and Annex II, which may be relevant to the classification of oil products are as follows:

- Any substitution of an existing component, or introduction of additional new components, to a preparation will require a new evaluation of health hazards. Changes to the amounts of existing components may prompt a re-evaluation, subject to the conditions given in Article 6, Part 4. (Note that this provision also applies to the re-evaluation of environmental hazards as given in Article 7; see section 6.5 of this report.)
- Classification of preparations containing low viscosity hydrocarbon components classified for aspiration hazard (Xn, R65), is subject to both a concentration limit (10% (w/w)) and viscosity (7cSt @40°C) criteria (See Annex II, Part A, 3.2 and section 6.1 of this report).
- Preparations containing a substance classified as carcinogenic, mutagenic or toxic for reproduction [Categories 1, 2 or 3] are automatically classified if the amount exceeds the appropriate concentration limits - see Annex II, Part A, 7, 8 and 9 and Annex II, Part B, 6. This applies even if data obtained by testing a preparation suggest no hazard.
- Sensitising, carcinogenic, mutagenic and toxic for reproduction hazards are not considered ‘additive’ for the purposes of classification. Hence there are no cumulative formulae in Annex II, Part A for these endpoints. Classification is therefore based on the presence of single components at more than the specified, or default concentration limits.
- For certain risk phrases (e.g. R33 and R64), special provisions apply. These are detailed in Annex V.
- For risk phrases R66 and R67 no default concentration limits have been established at the time of publication of this report. Discussions are ongoing at EU level to consider whether it is necessary to establish a default concentration limit for R67. In the absence of agreed default limits, or specific limits in Annex I to the DSD, application of these R phrases to preparations should be based on the criteria which appear in Annex VI to the DSD.
- Both R66 and R67 are "additional" risk phrases, which do not themselves result in classification of substances or preparations as dangerous, nor do they require application of a danger symbol. (See sections 6.2 and 6.3 of this report.)

2.7. ARTICLE 7 - EVALUATION OF ENVIRONMENTAL HAZARDS

Directive 1999/45/EC requires preparations to be evaluated for classification as "Dangerous for the Environment" (DFE) and, if necessary, to carry the "dead fish/dead tree" hazard symbol, based on the amount of DFE classified components they contain, or their intrinsic properties. [DFE classifications have applied to substances since 1994 with the introduction of the 18th Amendment to Technical Progress [4] (ATP) to the DSD.]

This article details the new requirement to apply DFE classifications and "dead fish/dead tree" hazard symbol to preparations. It comprises the following environmental classifications:

Aquatic toxicity

R50 "Very toxic to aquatic organisms"
R51 "Toxic to aquatic organisms"
R52 "Harmful to aquatic organisms"
R53 "May cause long-term adverse effects in the aquatic environment"

The basic criteria for aquatic toxicity classification are defined in the 18th ATP to the DSD. The risk phrases R50, R51 and R52 are based on the results from three acute toxicity tests on algae, daphnia and fish. The risk phrase R53 is based on available evidence for the substances contained in a preparation regarding their persistence, potential to accumulate and environmental fate.

Ozone layer damage

R59 "Dangerous for the ozone layer"

There are no test criteria in the DSD for R59. Substances that have been agreed and assigned with R59 classification are listed in Annex I to the DSD.

Terrestrial environment

R54 "Toxic to flora"
R55 "Toxic to fauna"
R56 "Toxic to soil organisms"
R57 "Toxic to bees"
R58 "May cause long-term adverse effects in the environment"

There are currently no criteria for classifying substances for the terrestrial environmental hazards in the DSD, and there are no criteria for classifying preparations in this Directive (Annex III part A section (b) 2). Currently, these classifications are not applied to any petroleum substances.

Classifying preparations for aquatic toxicity hazards

Directive 1999/45/EC gives 'conventional' method rules for assessing the DFE classification of preparations for aquatic toxicity (Annex III part A sections (a) 1 to 6) and ozone layer damage (Annex III part A section (b) 1). These are based on threshold amounts of component substances having DFE classifications. Possible classifications are:

N, R50 or N, R50-53
N, R51-53
R52 or R52-53
R53
N, R59
R59

(Where "N" denotes the application of the "dead fish/dead tree" hazard symbol and indication of danger "Dangerous for the Environment" on the hazard label. Where "N" is not assigned, only the R-phrases appear on the label.)

An algorithm is given (**Figure 1**) which enables an environmental classification for a preparation to be derived. This process is complicated by the fact that most petroleum substance DFE classifications are combinations of either R50, R51 or R52 with R53. The DPD does not allow for an R51 classification on its own, only in the combination R51-53.

These classifications are additive, so the amounts of DFE classified components must be added together as indicated in the algorithm. The classification threshold amounts shown in the algorithm (denoted by $^{\#}$) are the default limits given in Annex III part B tables 1 to 4. Where individual component substances are subject to specific concentration limits (specified in Annex I to the DSD), those concentration limits should be substituted.

A preparation which is classified by a 'conventional' method with either R50, R51 or R52 can be overridden where the three tests specified in the DSD (acute toxicity to algae, daphnia and fish) have been carried out on the preparation and the results fall outside the DSD classification criteria (Note: these tests must be conducted to Good Laboratory Practice standards). Where aquatic toxicological data exists for a preparation it may be possible to use it to "read across" to classify another preparation where there is good scientific justification for the comparison.

The R53 classification based on biodegradability and bioaccumulation cannot be overridden by testing of a preparation (Annex III part C).

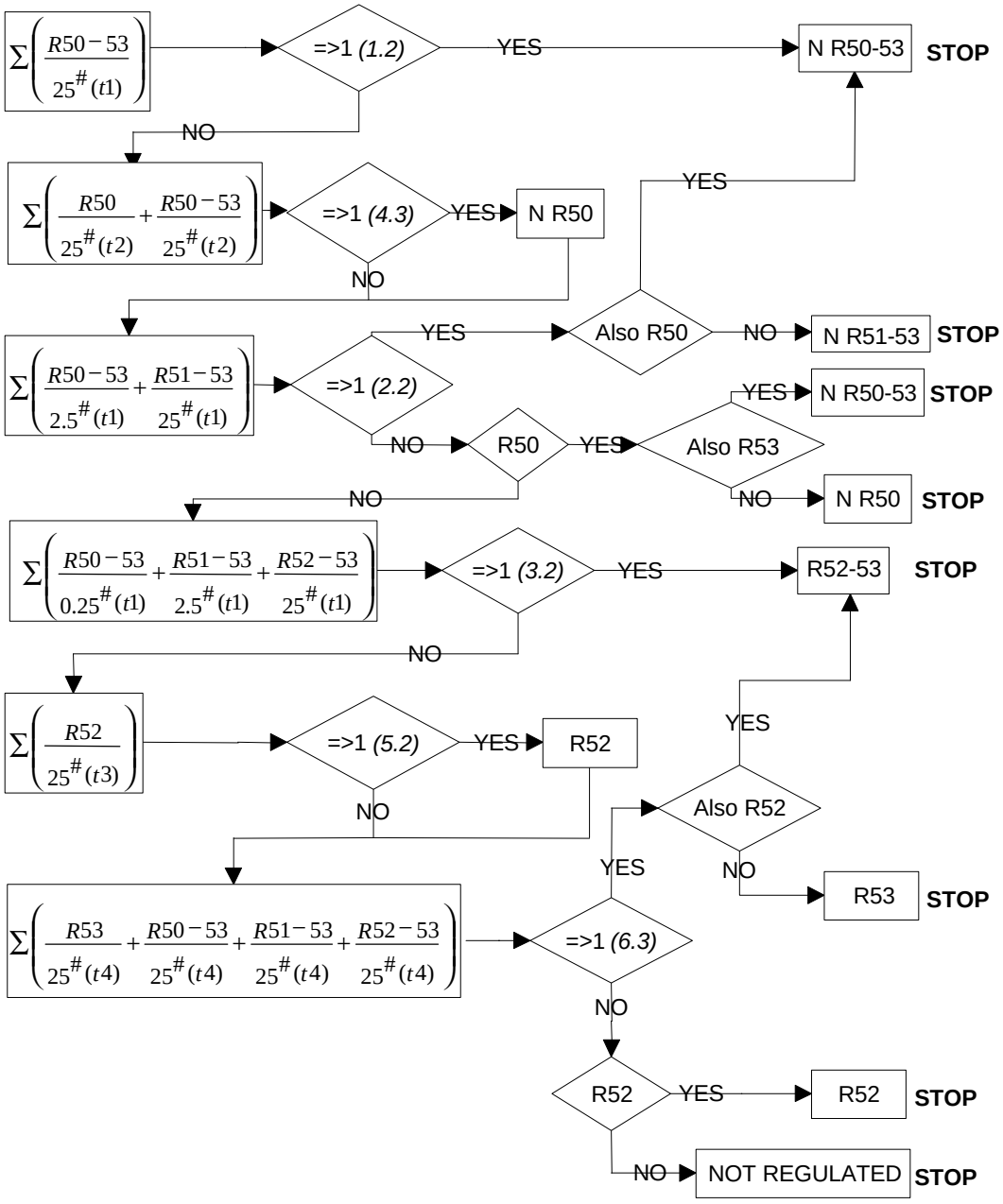
It should be noted that it is possible for a preparation to be classified as both N, R50 and N, R51/53 under the conventional method rules. It is recommended that in such cases the preparation be classified as N, R50/53.

Classifying preparations for ozone damage hazard

Preparations must be classified as R59 (or N, R59) if they contain 0.1% (w/w), or greater, of any component substance which is classified R59 (or N, R59). This classification is not additive, so the amounts of individual component substances are not added together (Annex III part A section (b) 1 and (b) 2).

FIGURE 1

CLASSIFICATION ALGORITHM FOR "DANGEROUS FOR THE ENVIRONMENT"



To use this algorithm, enter the weight percent of each substance classified with the R-phrases shown, into the above equations

Numbers in brackets preceded by t... refer to table numbers in the directive
Numbers in brackets not preceded by t... refer to section numbers in Annex III part A.

 # Where substances have individual concentration limits in Annex 1 to DSD, these should be used

2.8. ARTICLE 8 - OBLIGATIONS AND DUTIES OF THE MEMBER STATES

Those manufacturers placing preparations on the market are required to hold at the disposal of the authorities of the Member States the information used for the classification and labelling of the preparation. Member States can request this information at any time.

Where the national authority has sufficient grounds for doubting the security of the child-proof fastening (for those preparations where child-resistant fastenings are required (see Article 9)), the authority may ask the person responsible for placing the preparation on the market for a certificate from a test house (conforming with European Standards Series EU 45000) which certifies that either:

- the type of closure is such that it is not necessary to test to the ISO and CEN standards (referred to in Article 9)

  or,

- the closure has been tested and has been found to conform with the ISO and CEN standards (referred to in Article 9).

2.9. ARTICLE 9 - PACKAGING

For a preparation containing at least one dangerous substance and classified as a "dangerous preparation", compliance with the packaging requirements for carriage of dangerous goods by rail, road, inland waterway, sea or air is considered to satisfy the packaging requirements of the DPD. However, a supply label is still required.

The packaging of preparations containing at least one substance classified as sensitising and being present in a concentration equal to or greater than 0.1% (w/w), or in a concentration equal to or greater than that specified under a specific note for the substance in Annex I to the DSD, must bear the inscription:

'Contains (name of sensitising substance). May produce an allergic reaction.'

All containers, offered or sold to the general public, containing preparations classified and labelled for aspiration hazards (Xn, R65) must be fitted with child-resistant fastenings (with the exception of those preparations placed on the market in the form of aerosols or in a container with a sealed spray attachment).

All containers, offered or sold to the general public, containing preparations labelled as very toxic, toxic, or corrosive are to be fitted with child-resistant fastenings.

Child-proof fastenings on reclosable packages shall comply with ISO standard 8317 [13]. Child-proof fastenings on non-reclosable packages shall comply with CEN standard EN 862 [14].

Containers of whatever capacity, containing preparations offered or sold to the general public and labelled as very toxic, toxic, corrosive, harmful, extremely flammable, or highly flammable are to carry a tactile warning of danger (i.e., an embossed triangle) intended to warn persons who are visually impaired. The technical specifications for tactile warnings shall conform with EN standard 11683 [15].

2.10. ARTICLE 10 - LABELLING

All preparations classified as dangerous must be labelled according to the requirements of Directive 1999/45/EC. The requirement that the chemical names of substances which carry T+, T, Xn and C as indications of danger and which are present in concentrations above the lowest concentration limit (limit Xn or limit Xi), should be indicated on the label remains unchanged. However, there has been a revision of the criteria for identifying dangerous substances on the label when they are present in a preparation above their respective concentration limits. The Directive 1999/45/EC requires that products classified in the following danger categories must be identified by an internationally recognised system of nomenclature on the label:

- carcinogen,
- mutagen,
- toxic for reproduction,
- very toxic, toxic or harmful due to non-lethal effects after a single exposure,
- toxic or harmful due to severe effects after repeated or prolonged exposure,
- sensitising.

Because of this revision, substances which carry the newer risk phrases for reproductive toxicity (R60, R61, R62, and R63), are now automatically included in these categories of substances to be identified on the label.

It is now explicitly indicated that the names of substances which led to the classification of the preparation in the following danger categories need not be mentioned on the label (unless the substance also falls into other danger categories):

- explosive,
- oxidising,
- extremely flammable,
- highly flammable
- flammable,
- irritant,
- dangerous for the environment.

There is no change in the selection of danger symbol(s) and indication of danger, except that it is now indicated that the use of the symbol Xn makes the symbol Xi optional.

As a general rule, a maximum of six single or combined R phrases (compared with a maximum of four in Directive 88/379/EEC) are deemed sufficient to describe the risks. In some cases more than six R phrases may be necessary. Similarly, a maximum of six single or combined S phrases (compared with a maximum of four in Directive 88/379/EEC) are deemed sufficient to formulate the most appropriate safety advice. However, in some cases more than six S phrases may be necessary.

A new section is included which leaves the option for the EU authorities to indicate in future Adaptations to Technical Progress possible exemptions to environmental labelling, where it can be demonstrated that there would be a reduced environmental impact. The exemptions will be listed in Annex V of the DPD.

The following rules for indicating certain categories of danger may now be followed on labels of packages of 125 ml or smaller:

	Labelling required		
Classification of the preparation	**R phrase**	**S phrase**	**Symbol**
Highly flammable	no	no	yes (F)
Flammable	yes	no	no
Oxidising	no	no	yes (O)
Irritant –except R41	no	no	yes (Xi)
Dangerous for the environment -N symbol	no	no	yes (N)
Dangerous for the environment - no N symbol	yes	no	no

On packages of preparations, indications such as "non-toxic", "non-harmful", "non-polluting", "ecological" may not be shown, nor any other statement included which suggests that the preparation is not dangerous, or lead one to underestimate the dangers. This applies to "any preparation subject to this Directive". Certain groups of products are excluded in Article 1 (e.g. medicinal, cosmetic and food products and wastes). However, member companies are recommended to seek legal advice prior to applying any such indications on packages of non-dangerous preparations of petroleum products. [Note that theoretically this requirement could be in conflict with some national ecolabelling schemes which have exempted certain hazard characteristics of products.]

2.11. ARTICLE 11 - IMPLEMENTATION OF THE LABELLING REQUIREMENTS

There are no changes to the implementation of the labelling requirements laid out in Directive 88/379/EEC apart from a new requirement that the information required on the label under Article 10 shall stand out clearly from its background and shall be of such size and spacing as to be easily read.

While Member States may make the placing on the market of preparations covered by the DPD within their territories subject to use of their official language or languages, Directive 1999/45/EC does not require, nor prohibit, the use of multi-lingual labels.

2.12. ARTICLE 12 - EXEMPTIONS FROM THE LABELLING AND PACKAGING REQUIREMENTS

Packaging and labelling requirements need not apply to certain dangerous preparations defined in Annex VII, which do not present any physico-chemical risk, or risk to health or to the environment in the form in which they are placed on the market.

Annex VII makes reference to paragraph 9.3 of Annex VI of the DSD. This applies to preparations which are alloys, or which contain polymers or elastomers. Such preparations need to be classified according to the standard procedures. Also, the procedures for providing safety data sheets to the professional user need to be observed. However, such preparations need not to be labelled if they do not present a danger to human health or the environment in the form which they are placed on the market. Examples of such preparations include solid plastic and rubber articles.

Member States may permit that containers need not be labelled, or be labelled in some other way if:

(a) packages are either too small or otherwise unsuitable for labelling,
(b) quantities of harmful, extremely flammable, highly flammable, flammable, irritant or oxidising preparations are so small that there is no fear of danger in handling,
(c) quantities of dangerous preparations are so small that there is no fear of danger to the environment,
(d) quantities of preparations that are labelled in some other way are so small that there is no fear of danger for handling.

Note that (c) and (d) are new exemptions.

The exemptions from labelling shall appear in Annex V of the DPD (Special provisions concerning the labelling of certain preparations).

2.13. ARTICLE 13 - DISTANCE SELLING

Any advertisement for a preparation within the scope of the DPD which enables a member of the general public to conclude a contract for purchase of such preparation without first having sight of the label for that preparation must make mention of the type(s) of hazard indicated on the label. The key words of the text are "advertisement", "preparation", "enables", "member of the general public" and "conclude".

On the basis of a legal opinion provided to CONCAWE, it would appear that where an advertisement for a preparation enables a member of the general public to order that preparation by telephone, fax, e-commerce, mail, etc., the seller would be required to inform the buyer, in advance of concluding a contract for purchase, of the type(s) of hazard on the product label. An example of this would be a website (which, it is commonly held, is an advertisement) which allows for on-line purchasing of a preparation.

In contrast, where an advertisement for a preparation does not enable a member of the general public to conclude a contract, product label disclosure is not necessary. Examples of this would include billboards, pole signs, as well as magazine and television advertisements which do not have, for example, an order form or an order line telephone number.

This interpretation could vary from country to country based on Member State transposition of the distance selling provision into national regulation. Member companies should therefore clarify the applicable interpretation in countries where they conduct retail operations.

2.14. ARTICLE 14 - SAFETY DATA SHEET

Under Directive 88/379/EEC, Member States were required to ensure that a system be set up for the mandatory supply of SDSs to professional users for all preparations classified as dangerous. This still applies, but Article 14 now extends the requirement to give professional users the right to be supplied, on request, with SDSs containing proportionate information for certain non-dangerous preparations. This extension covers those preparations not classified as dangerous by the DPD, but, nevertheless, containing at least one substance:

- that poses health or environmental hazards, or ,
- for which there are Community workplace exposure limits (OELs) in place,

and

where the concentration of any such individual component is 1% (w/w) or greater for non-gaseous preparations, or 0.2% (vol/vol) or greater for gaseous preparations.

As a consequence, CONCAWE member companies will need to have SDSs available for all products which meet the criteria specified above, so that sheets can be provided on request.

For the petroleum industry, the provision of safety data sheets for non-dangerous preparations has significant implications. For example, several different lubricant formulations may be sold under a single product name, all of which are non-hazardous according to the DPD, but each containing different hazardous components at the 1% (w/w) concentration level or above. Provision of separate SDSs for each formulation may not be practicable and could even confuse. Generic SDSs may be more suitable particularly if coupled with formulation specific information on the label - for example the sensitisers present (if above 0.1% (w/w)), batch number, or date and place of manufacture.

The appropriate annex to Directive 91/155/EEC [16] covering the format of SDSs is to be amended by 30 July 2002 to include the provision of SDSs for non-dangerous preparations. An ad-hoc Commission group is currently examining what proposal should be made.

2.15. ARTICLE 15 - CONFIDENTIALITY OF CHEMICAL NAMES

The provision to use generic chemical names for confidentiality reasons when disclosing dangerous components on labels and data sheets is now restricted to substances with certain harmful and irritant classifications. It now applies only to components classified as Xn R20, R21, R22, Xn R65 and Xi R36, R37, R38. Further, generic chemical names may not be used for substances which have an EU exposure limit.

Previously a supplier was permitted to use generic names, where applicable, with the only duty required being to inform the competent authority in the Member State where the preparation was first put on the market. No provisions were made to define acceptable generic names.

Directive 1999/45/EC now requires a supplier to request permission to use a generic name in applicable cases from the competent authority in the Member State where the preparation was first put on the market, using a specified procedure which includes a list of information that must be provided (Annex VI part A). The supplier must forward a copy of this permission to each of the Member States where the product is to be marketed subsequently.

The Directive also details a generic substance naming system which must be used (Annex VI part B). It contains a list of 22 generic names for the types of petroleum substances (Annex VI part B 3, Family no. 649) included in Annex I to the DSD.

As these generic, or group, names appear in Annex I to the DSD, they can be used on labels or in the SDSs, to identify hazardous petroleum substances present in preparations. For other hazardous petroleum substances (e.g. straight-run gas oils)

which do not appear in Annex I, the component should be described using an internationally recognised chemical nomenclature. If a supplier wishes however to use an alternative name (e.g. a generic group description), then appropriate permission will need to be sought from a Member State. For other hazardous components, suppliers of preparations will need to discuss the use of generic names with their relevant component suppliers.

2.16. ARTICLE 17 - BODIES RESPONSIBLE FOR RECEIVING INFORMATION RELATING TO HEALTH

Member States are to ensure that bodies, for example: poison centres, are appointed to receive information on products considered dangerous based on their health effects or on the basis of their physico-chemical effects. However, the nature and amount of information to be provided is not defined.

Provision of environmental hazard information is not required.

2.17. ARTICLE 20 - ADAPTATION TO TECHNICAL PROGRESS

In drafting the new DPD, the Commission took the opportunity to ensure that, as far as possible, technical issues were included in Annexes to the Directive, rather than in the main text. As a result, a much simpler process can be adopted for subsequent amendment of these technical issues. Article 20 provides a framework for the technical adaptation of the Annexes. In essence, decisions can be taken by a Technical Progress Committee, subject to normal EU qualified majority voting rules. It is likely that a working group, comprising representatives of Member States, Industry and Trade Unions, will be established to assist the Commission in formulating technical adaptation proposals to this Directive.

2.18. ARTICLE 21 - REPEAL OF DIRECTIVES

The Directives listed below are repealed although there are arrangements for specific detailed minor exceptions to continue for Austria, Finland and Sweden.

Directive 78/631/EEC - relating to the classification, packaging and labelling of dangerous preparations (pesticides)

Directive 90/35/EEC - relating to category of preparations the packaging of which must be fitted with a child resistant fastenings and/or carry a tactile warning

Directive 91/442/EEC - relating to dangerous preparations of which must be fitted with child resistant fastenings

Directive 88/379/EEC - relating to classification, packaging and labelling of dangerous preparations including its adaptations to technical progress:

- Directive 89/178/EEC
- Directive 90/492/EEC
- Directive 93/18/EEC
- Directive 96/65/EC

3. IMPLEMENTATION DATES

The key implementation date for the petroleum industry is 30 July 2002 by which time Member States are required to apply the laws, regulations and administrative provisions referred to in this Directive to all preparations which are outside of the scope of the Directive on plant protection products (91/414/EEC) [17] or of the Directive on biocidal products (98/8/EC) [18].

For those preparations related to the plant protection products and biocidal products, Member States are required to apply the laws, regulations and administrative provisions necessary to comply with this Directive from 30 July 2004.

4. PROPORTIONATE INFORMATION ON SDS FOR NON-CLASSIFIED PREPARATIONS

The Commission established a working group in December 1999 to agree the content of an adaptation to technical progress to Directive 91/155/EEC defining the specific nature of 'proportionate information' in SDSs. The Commission envisages that the ATP to Directive 91/155/EEC would be forwarded to the Technical Progress Committee by the summer of 2001.

Directive 1999/45/EC also calls for Member States to take the necessary measures to ensure that the person responsible for placing a preparation which is not classified as dangerous but contains a substance in an individual concentration of ≥1% (w/w), or ≥0.2% (vol/vol) for gaseous preparations, which either:

- poses a health or environmental hazard, or

- for which there is a Community workplace exposure limit (OEL)

provides an SDS containing 'proportionate information' at the request of a professional user.

5. NOTES ON ANNEXES

5.1. ANNEX I PART B.2 - METHODS FOR THE EVALUATION OF PHYSICO-CHEMICAL PROPERTIES OF PREPARATIONS / ALTERNATIVE CALCULATION METHODS

Directive 1999/45/EC contains a reference (in Annex I part B.2) to a provision to permit the calculation of flammability for gas mixtures in certain circumstances. However, the reference is to a provision which already applies for gas mixtures, in Annex VI to DSD, section 9.1.1.1 (latest version is in the 18th ATP to the DSD).

The provision in the DSD applies to gas mixtures which are produced to order in small amounts, whereas the provision in the new DPD applies to gas mixtures for which the specified flammability test methods are inappropriate.

Flash point test methods are specified in Annex V to the DSD (the latest version of this Annex is in the 17th ATP [8] to the DSD) and include ABEL, ABEL-PENSKY, TAG and PENSKY-MARTENS.

The procedure to calculate flammability for gas mixtures given in Annex VI to the DSD is based on the molar fractions of each flammable and inert gas component of the mixture.

5.2. ANNEX V - SPECIAL PROVISIONS CONCERNING THE LABELLING OF CERTAIN PREPARATIONS

Annex V outlines special labelling provisions that are applied to certain types of preparations. All these special labelling requirements are applicable to petroleum products, if the stated conditions are met. Many of these provisions are unchanged from Annex II of Directive 88/379/EEC as adapted for the third time by Directive 93/18/EEC [19]. The new provisions in Annex V of the DPD can be summarised as below.

- Section B7: preparations available as aerosols:

  This requires all preparations supplied as aerosols to be labelled in accordance with the Aerosol Directive 75/324/EEC, as last amended by Directive 94/1/EC, as well as including any labelling requirements under the DPD.

- Section B8: preparations containing substances not yet fully tested.

  If a preparation contains 1% (w/w), or greater, of a substance bearing the inscription ‘Warning - substance not yet tested completely’, the label of the preparation must bear the inscription ‘ Warning - this preparation contains a substance not yet tested completely.’ This requirement applies to all preparations whether or not they are classified as dangerous.

- Section B9: preparations not classified as sensitising, but containing at least one sensitising substance.

  If a preparation contains a sensitiser at a concentration of 0.1% (w/w), or greater, or at a concentration equal to or greater than that specified under a specific note for the substance in Annex I of the DSD, then the packaging for

the preparation must bear the inscription ‘Contains (name of sensitising substance). May produce an allergic reaction’.

- Section B10: liquid preparations containing halogenated hydrocarbons.

  If a liquid preparation contains a halogenated hydrocarbon and more than 5% (w/w) of flammable or highly flammable substances, but shows no flash point or has a flash point higher than 55°C, then the packaging must bear the inscription ‘Can become highly flammable in use’ or ’Can become flammable in use’ as appropriate.

- Section C1: preparations not intended for the general public.

  For preparations not classified as dangerous, but containing at least one dangerous substance as referred to in Article 14.2.1(b), the label on the packaging must bear the inscription ‘Safety data sheet available for professional users on request’. This inscription is not required for preparations sold only to the general public.

6. SPECIFIC ISSUES OF RELEVANCE TO THE OIL INDUSTRY

6.1. ASPIRATION HAZARD (R65)

Low viscosity petroleum substances (for example, low boiling point naphthas, kerosines and gas oils) present an aspiration hazard due to their potential to cause chemical pneumonitis if they enter the lungs in liquid form. Hydrocarbons having a kinematic viscosity of less than 7 cSt at 40°C have been identified as posing a significant aspiration hazard.

The 22nd ATP [5] to the DSD introduced a risk phrase R65 (Harmful: may cause lung damage if swallowed) for aspiration hazard together with criteria which determine whether substances or preparations should be classified. The essential criteria as finally specified in the 25th ATP [6] to the DSD are as follows:

- They must contain more than 10% (w/w) hydrocarbons, and
- the viscosity must be below 7 cSt at 40°C
- optionally the surface tension must not be greater than 33 mN/m at 25°C

Where human experience shows that a substance or preparation presents an aspiration hazard, it must be classified and labelled accordingly, regardless of whether the criteria are met.

CONCAWE does not support the use of surface tension to avoid classification.

6.2. SKIN DRYNESS OR CRACKING (R66)

The 25th ATP of the DSD introduced the risk phrase R66 (Repeated exposure may cause skin dryness or cracking) for substances and preparation that do not meet the criteria for R38 but which may cause concern as a result of the ability to cause skin dryness, flaking or cracking. Decisions for applying this risk phrase are derived either from practical observation after normal handling and use, or from relevant information used to predict effects on the skin.

Certain low viscosity substances (e.g., fuel oils and gas oils) of lower molecular weight and higher aromaticity are considered likely to be irritant to skin and warrant the use of the R66 phrase. Preparations which include these types of substances should be evaluated on a case by case basis to see if the criteria for assigning the R66 to the preparation are met.

Note: R66 is a supplemental risk phrase that does not result in classification of materials as dangerous, nor does it require application of a danger symbol.

6.3. DROWSINESS AND DIZZINESS (R67)

The 25th ATP of the DSD also introduced the risk phrase R67 (Vapours may cause drowsiness and dizziness). This applies to volatile substances and preparations containing substances that cause clear symptoms of central nervous system depression by inhalation and which are not already classified with respect to acute inhalation toxicity (R20, R23, R26, R40/20, R39/23 or R39/26). In the absence of any specified concentration limits, preparations containing volatile substances for

which R67 has been applied need to be considered on a case by case basis to determine whether criteria for assigning R67 to the preparation are met.

The following evidence should be considered:

(a) data from animal studies showing clear signs of CNS depression such as narcotic effects, lethargy, lack of co-ordination (including loss of righting reflex) and ataxia either:

- at concentration/exposure times not exceeding 20 mg/l/4 h or,
- for which the ratio of the effect concentration at ≤ 4 h to the saturated vapour concentration (SVC) at 20°C is ≤ 1/10.

(b) Practical experience in humans (e.g. narcosis, drowsiness, reduced alertness, loss of reflexes, lack of co-ordination, vertigo) from well documented reports under comparable exposure conditions to the effects specified above for animals.

At the time of publication of this report, a 15% (w/w) concentration limit is being discussed by a Commission work group. If agreed, this would mean that the R67 phrase would need to be assigned to a preparation if the concentration of a substance which carries the R67 phrase is present in a concentration of 15% (w/w), or greater, in the preparation.

Note: R67 is a supplemental risk phrase that does not result in classification of materials as dangerous, nor does it require application of a danger symbol.

6.4. CLASSIFICATION OF PREPARATIONS MADE FROM OTHER PREPARATIONS OR SUBSTANCES WITH HAZARDOUS INGREDIENTS

A preparation such as a lubricating oil is typically formulated from substances (such as basestocks) and preparations (such as additive packages).

Where the final product classification is derived from the classification of additives which are preparations, this should not be based on the classification of the additive packages themselves, but on the classifications and amounts of their hazardous ingredients.

EXAMPLE: An oil formulated with 11% (w/w) of an additive classified as severe eye irritant R41, based on it containing 20% (w/w) of a zinc dialkyl dithiophosphate (ZDDP) classified as R41. If the oil's classification were based on the classification of the additive, it would be wrongly classified as irritant R41 (the threshold amount is 10% (w/w) for this classification). The oil's classification should be based on the amount of the ZDDP hazardous ingredient in the final product, in this case 20% of 11% = 2.2% (w/w) which results in no classification for the final product.

A preparation such as a petroleum fuel is typically blended from streams which are substances, and minor amounts of additives.

Where a preparation contains a substance which is classified on the basis of its content of a hazardous ingredient which is the subject of a specific nota in the DSD (such as benzene and butadiene), the derivation of the preparation's classification is not clear in the regulations.

EXAMPLE: A fuel formulated with 5% (w/w) of a stream containing 1% (w/w) benzene and consequently classified as carcinogenic R45 (the threshold amount is 0.1% (w/w) for this classification). If the fuel's classification were based on the stream's classification then the fuel would be classified as carcinogenic R45, even though its benzene content (1% of 5% = 0.05%) was below the 0.1% (w/w) classification threshold amount for R45. In such cases there is inconsistency between the DSD and the DPD, as Nota J in the 21st ATP [20] to the DSD allows certain petroleum substances not to be classified as carcinogenic if they contain less than 0.1% (w/w) benzene.

This can obviously lead to a situation where repeated dilution of a benzene containing stream with a non-benzene containing stream could result in a fuel containing virtually no benzene, but still classified as carcinogenic R45 based on the benzene in the initial stream. Consequently it is common practice to base such a classification on the benzene content of the final product.

6.5. ASSESSMENT OF HEALTH AND ENVIRONMENTAL HAZARDS - 'READ ACROSS'

Articles 6 and 7 provide for the use of either a 'conventional' method, or testing using approved methods, to evaluate the health or environmental hazards of a preparation. Both of these articles also indicate that changes in the composition of preparations, including both quantitative changes and the inclusion of new or substituted components, may not need to be re-evaluated, providing there is valid scientific justification for considering that the hazards will not change. Furthermore, for certain health hazards, it is possible to use human data, or scientific data suggesting potentiation or antagonism, to modify the health classification of a preparation.

In assessing the health and environmental hazards of a new preparation, valuable information can be obtained from experimental data available on other preparations, which are closely similar in composition, or contain similar components. This process is commonly known as 'read across'. For example, experimental data on a formulated product containing one component at 30% which is classified as harmful, can be used as a basis for not classifying the preparation. These data could also be used as scientific justification for 'read across' to other formulations which contain less than 30% of the same component, provided the other components do not contribute to the toxicity of the product.

Data on one formulation could also be used as the basis to justify scientifically a decision not to classify a family of closely related products (e.g. gear oils) where the compositional changes are small or involve the introduction of chemically similar components which are not classified as hazardous.

Test data on products containing components which are classified as skin sensitisers is another potential application of 'read across', as for example, in the use of biocides in metal working fluids. Test data can be used to establish a safe working concentration at which skin sensitisation would be considered unlikely to occur. These data can be used as a basis for 'read across' to other products containing similar levels, but differences in physico-chemical properties of the products, and their influence on exposure/absorption, need to be considered carefully. It needs to be recognised however that, even though a product may not need to be classified as a skin sensitiser, there may be a need to warn users, e.g. in the SDS, that it contains small amounts of a sensitising component.

Application of a scientifically based ‘read across’ argument for evaluating the classification of preparations also meets the principle of minimising animal testing and the requirements of Directive 86/609/EEC [21] on animal protection.

6.6. TESTING VS. 'CONVENTIONAL' METHOD

The health and environmental hazards of a preparation can be evaluated by either a 'conventional' method or by testing the preparation using one of the experimental methods given in Annex V to Directive 67/548. Application of 'conventional' method rules for classification is discussed under Articles 6 and 7.

In general, classifications derived using test data override those given by the ‘conventional’ method. There are however a number of exceptions to this. Any preparation containing more than the specified amount of a component, which is classified as a carcinogen, mutagen or reproductive toxicant, must be classified using a 'conventional' method. Test data on the preparation cannot override this. Preparations containing more than the specified amount of components which are not readily biodegradable or that bioaccumulate, must also be classified using a ‘conventional’ method (i.e. you cannot test preparations for biodegradability or bioaccumulation). Furthermore, for acute aquatic toxicity, preparations must be tested in all 3 aquatic species, with the lowest result being used as the basis for classification.

Application of a 'conventional' method may, however, either under or overestimate the health or environmental hazards of a preparation. Differences may occur for a variety of reasons (e.g. chemical reactions may occur and the resulting substances may be more or less hazardous than the starting components, physical form or properties of the preparation may influence uptake). In these circumstances, testing for a given endpoint could be justified, as results would provide a more reliable basis for classification. Before proceeding with test work, suppliers need to review the available information and decide whether there is a scientifically valid argument to suggest that testing would give a different answer to that from a 'conventional' method. As part of this evaluation, suppliers need to consider carefully the general EC requirement to reduce the number of animals being used in experiments, as well as cost and time elements. Having decided to proceed, suppliers need to document their rationale, undertake studies which are in compliance with the latest guidelines and also comply with Good Laboratory Practice requirements.

6.7. PLACING ON THE MARKET

Article 2 defines the term ‘Placing on the Market’ as meaning making available to third parties, including importation into the Community customs territory. This means that any person or organisation making a preparation available to a 3rd party, regardless of whether money has been received, may have obligations to that 3rd party under the DPD.

In the oil industry, the supply/logistics chain may be extremely long and complex. All parties involved need to recognise their responsibilities under the DPD. Suppliers of components and or formulated products need to satisfy the requirements of the DPD with regard to product packaging, hazard labelling, SDSs etc. and make sure that appropriate information is provided to the next party in the supply chain. If the logistics/supply chain includes agents, distribution warehouses, marketing distribution companies, or importation into other countries, then it is important that

these organisations are provided with information to enable them in turn to meet their obligations as bodies ‘placing preparations on the market’.

CONCAWE recommends that member companies review their supply/logistic arrangements to ensure that information is passed along the supply chain and that all parties recognise their obligations under the DPD.

7. REFERENCES

1. EU (1999) Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (1999/45/EC). Official Journal of the European Communities No. L200, 30.07.1999

2. EU (1988) Council Directive of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (88/379/EEC). Official Journal of the European Communities No. L187, 16.07.1988

3. EU (1967) Council Directive of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (67/548/EEC). Official Journal of the European Communities No. L196, 16.08.1967

4. EU (1993) Commission Directive 93/21/EEC of 27 April 1993 adapting to technical progress for the 18th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Official Journal of the European Communities No. L110, 04.05.1993

5. EU (1996) Commission Directive 96/54/EC of 30 July 1996 adapting to technical progress for the 22nd time Council Directive 67/548/EC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Official Journal of the European Communities No. L248, 30.09.1996

6. EU (1998) Commission Directive 98/98/EC of 15 December 1998 adapting to technical progress for the 25 time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Official Journal of the European Communities No. L 355, 30.12.1998

7. EU (1992) Council Directive 92/32/EEC of 30 April 1992 amending for the 7th time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Official Journal of the European Communities No. L154, 05.06.1992

8. EU (1992) Annex to Commission Directive 92/69/EEC of 31 July 1992 adapting to technical progress for the 17th time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Official Journal of the European Communities No. L383A, 29.12.1992

9. EU (1988) Commission Directive 87/302/EEC of 18 November 1987 adapting to technical progress for the ninth time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Official Journal of the European Communities No. L133, 30.05.1988

10. EU (2000) Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the 26th time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Official Journal of the European Communities No. L136, 08.06.2000

11. EU (1975) Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the relating Member States to aerosol dispensers. Official Journal of the European Communities No. L147, 09.06.1975

12. EU (1994) Commission Directive 94/1/EC of 6 January 1994 adapting some technicalities of Council Directive 75/324/EEC on the approximation of the laws of the relating Member States to aerosol dispensers. Official Journal of the European Communities L23, 28.01.1994

13. ISO (1989) Child-resistant packages - Requirements and methods of testing for reclosable packages. ISO 8317. Geneva: International Organization for Standardization

14. CEN (1997) Packaging - Child-resistant packaging - Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products. EN 862. Brussels: European Committee for Standardization

15. ISO (1997) Packaging - Tactile warnings of danger - Requirements. International standard ISO 11683. Geneva: International Organization for Standardization

16. EU (1991) Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC. Official Journal of the European Communities No. L076, 22.03.1991

17. EU (1991) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. Official Journal of the European Communities No. L230, 19.08.1991

18. EU (1998) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. Official Journal of the European Communities No. L123, 24.04.1998

19. EU (1993) Commission Directive 93/18/EEC of 5 April 1993 adopting for the third time to technical progress Council Directive 88/379/EEC on the approximation of the laws, regulations, and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations. Official Journal of the European Communities No. L104, 29.04.1993

20. EU (1994) Commission Directive 94/69/EC of 19 December 1994 adapting to technical progress for the 21st time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Official Journal of the European Communities No. L381, 31.12.1994

21. EU (1986) Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes. Official Journal of the European Communities No. L358, 18.12.1986

APPENDIX 1

DIRECTIVE 1999/45/EC

I

(Acts whose publication is obligatory)

DIRECTIVE 1999/45/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 31 May 1999

concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal of the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

(1) Whereas Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations [4] has been amended on several occasions; whereas on the occasion of further amendments, the said Directive should, for reasons of clarity, be recast;

(2) Whereas, in spite of Community provisions, the rules applying to certain dangerous preparations in the Member States exhibit considerable differences as regards classification, packaging and labelling; whereas these differences constitute a barrier to trade, create unequal competition conditions and directly affect the functioning of the internal market; whereas it is therefore necessary to remove this barrier to trade by approximating the relevant legislation existing in the Member States;

(3) Whereas measures for the approximation of the provisions of the Member States affecting the establishment and functioning of the internal market must, in so far as they concern health, safety and protection of man and the environment, adopt a high level of protection as a basis; whereas this Directive must, at the same time, ensure protection for the general public, and, in particular, persons who come into contact with dangerous preparations in the course of their work or in the pursuit of a hobby, protection for consumers and for the environment;

(4) Whereas containers containing certain categories of dangerous preparations offered or sold to the general public must be fitted with child-resistant fastenings and/or carry a tactile warning of danger; whereas certain preparations not falling within these categories of danger may nevertheless, owing to their composition, present a danger for children; whereas the packaging of such preparations should therefore be equipped with child-resistant fastenings;

(5) Whereas it is necessary to provide concentration limits expressed as a volume/volume percentage in the case of preparations marketed in gaseous form;

(6) Whereas this Directive contains special labelling provisions applicable to certain preparations; whereas, to ensure an adequate level of protection for man and the environment, special labelling provisions must also be introduced for certain preparations which, although not dangerous within the meaning of this Directive, may nevertheless present a danger to the user;

(7) Whereas on 30 April 1992 the Council adopted Directive 92/32/EEC amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [5]; whereas on 27 April 1993 the Commission adopted Directive 93/21/EEC [6] adapting

[1] OJ C 283, 26.9.1996, p. 1, and OJ C 337, 7.11.1997, p. 45.
[2] OJ C 158, 26.5.1997, p. 76.
[3] Opinion of the European Parliament of 26 June 1997 (OJ C 222, 21.7.1997, p. 26), Council common position of 24 September 1998 (OJ C 360, 23.11.1998, p. 1) and Decision of the European Parliament of 10 February 1999 (OJ C 150, 28.5.1999). Council Decision of 11 May 1999.
[4] OJ L 187, 16.7.1988, p. 14. Directive as last amended by Commission Directive 96/65/EC (OJ L 265, 18.10.1996, p. 15).
[5] OJ L 154, 5. 6. 1992, p. 1.
[6] OJ L 110, 4.5.1993, p. 20.

to technical progress for the 18th time Council Directive 67/548/EEC; whereas new criteria developed for classifying and labelling substances dangerous for the environment were introduced by those Directives, together with the appropriate symbols, indications of danger, risk phrases and safety advice required to appear on labelling; whereas provisions should be adopted at Community level on the classification and labelling of preparations to take account of their effects on the environment and whereas it is therefore necessary to introduce a method for assessing the hazards of a given preparation for the environment either by a calculation method, or by determining the ecotoxicological properties by test methods under certain conditions;

(8) Whereas the number of animals used for experiments should be reduced to a minimum, in accordance with the provisions of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes [1]; whereas Article 7(2) of that Directive stipulates that an experiment shall not be performed if another scientifically satisfactory method of obtaining the results sought, not entailing the use of an animal, is reasonably and practically available; whereas, therefore, this Directive makes use of the results of assessments of toxicological and ecotoxicological properties only when these are already known and entails no obligation to conduct further experiments on animals;

(9) Whereas it is necessary to define what human experience might be considered for the evaluation of the health hazards of a preparation; whereas, if clinical studies may be accepted, it is taken as given that such studies comply with the Helsinki Declaration and OECD Guidelines for Good Clinical Practice;

(10) Whereas the characteristics of alloys are such that it may not be possible accurately to determine their properties using currently available conventional methods; whereas it is therefore necessary to develop a specific method of classification which takes into account their particular chemical properties; whereas the Commission, in consultation with Member States, will examine this need and submit a proposal, if appropriate, before the implementation date of this Directive;

(11) Whereas classification, packaging and labelling of plant protection products covered by Council Directive 78/631/EEC of 26 June 1978 on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides) [2] need to be revised taking into account technical and scientific developments as well as regulatory developments following implementation of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [3];

(12) Whereas Directive 91/414/EEC and Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [4], in contrast to the provisions applicable to chemical preparations covered by this Directive, provide for an authorisation procedure for each product on the basis of a dossier presented by the applicant and an assessment carried out by the competent authority in each Member State; whereas furthermore that authorisation procedure includes a control relating specifically to the classification, packaging and labelling of each product before it is placed on the market; whereas it is appropriate, as part of a clear and transparent information process, to classify and label plant protection products according to the provisions of this Directive, and also to provide instructions for use in accordance with the results of the evaluation carried out in the framework of Directive 91/414/EEC and to ensure that the labelling satisfies the high level of protection sought by both this Directive and Directive 91/414/EEC; whereas, in addition, a safety data sheet has to be established for plant protectioon products in accordance with this Directive;

(13) Whereas it is appropriate to provide, in relation to environmental labelling, that specific exemptions or specific provisions may be decided upon in specific cases where it can be demonstrated that the overall environmental impact of the product types in question is lower than that of corresponding product types;

(14) Whereas, although munitions are not covered by this Directive, explosives marketed to produce an explosive or pyrotechnic effect may, through their chemical composition, present dangers to health; whereas it is therefore necessary as part of a transparent information process to classify them and assign to them a safety data sheet in accordance with the provisions of this Directive and also to label them in accordance with the international rules used for the transport of dangerous goods;

(15) Whereas, in order to take account of certain preparations which, although they are not considered dangerous under this Directive, may nevertheless present a danger for users, it is necessary to extend certain provisions of this Directive to cover such preparations;

[1] OJ L 358, 18.12.1986, p. 1.
[2] OJ L 206, 29.7.1978, p. 13. Directive as last amended by Council Directive 92/32/EEC.
[3] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 96/68/EC (OJ L 277, 30.10.1996, p. 25).
[4] OJ L 123, 24.4.1998, p. 1.

(16) Whereas the label constitutes a basic tool for users of the dangerous preparations in so far as it provides them with the initial essential concise information; whereas it nevertheless needs to be supplemented by a two-fold system of more detailed information, consisting firstly of the safety data sheet, intended for professional users as defined by Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC [1] and secondly of the bodies appointed by the Member States which are responsible for the provision of information solely for medical purposes, both preventive and curative;

(17) Whereas, on the basis of information to be supplied by the Member States and the various parties concerned, the Commission will submit a report to the European Parliament and the Council within two years of the entry into force of this Directive on experience with the present overall approach to labelling of dangerous preparations and in particular on its understanding and application by users, experience with publicity campaigns and educational and training programmes; whereas, on the basis of this report, the Commission will, if appropriate, submit the necessary proposals;

(18) Whereas it is necessary to require safety data sheets providing proportionate information on the dangers to man and the environment arising from preparations not classified as dangerous within the meaning of this Directive but containing substances classified as dangerous or having a Community exposure limit; whereas the Commission, on the basis of information submitted by Member States, will review Directive 91/155/EEC and submit proposals, if appropriate, before the expiry of the date for implementation of this Directive;

(19) Whereas, in the case of preparations classified as dangerous within the meaning of this Directive, it is appropriate to permit Member States to allow certain derogations with respect to labelling where the packaging is too small, or otherwise unsuitable for labelling, or where such small packaging or such small quantities are involved that there is no reason to fear any danger to man or the environment; whereas in such cases appropriate consideration should also be given to the approximation of the relevant provisions at Community level; whereas the Commission will therefore examine the needs for harmonisation and, if appropriate, submit proposals;

(20) Whereas the confidentiality of certain substances contained in the preparations should be guaranteed and whereas it is therefore necessary to institute a system which allows the person responsible for placing the preparation on the market to request confidentiality for such substances;

(21) Whereas the provisions of this Directive will have regard to the commitment entered into by the Community and its Member States, in accordance with the goals for sustainable development set under Agenda 21, Chapter 19, at the UNCED conference held in June 1992 in Rio de Janeiro, to strive for the future harmonisation of systems for the classification of dangerous substances and preparations;

(22) Whereas the Commission should be given the powers necessary to adapt all the Annexes to this Directive to technical progress;

(23) Whereas the adoption of this Directive should not affect the obligations of the Member States concerning the deadlines for transposition into national law and for application of the Directives indicated in Annex VIII;

(24) Whereas the Directives indicated in Annex VIII should be repealed, subject to certain conditions; whereas the conditions for repealing the Directives indicated in Annex VIII should be specified for Austria, Finland and Sweden in order to take account of the present level of their legislation, in particular as regards the protection of health and the protection of the environment,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Objectives and scope

1. This Directive aims at the approximation of the laws, regulations and administrative provisions of the Member States relating to:

— the classification, packaging and labelling of dangerous preparations, and to

— the approximation of specific provisions for certain preparations which may present hazards, whether or not they are classified as dangerous within the meaning of this Directive,

when such preparations are placed on the market of the Member States.

[1] OJ L 76, 22.3.1991, p. 35. Directive as last amended by Commission Directive 93/112/EEC (OJ L 314, 16.12.1993, p. 38).

2. This Directive shall apply to preparations which:

— contain at least one dangerous substance within the meaning of Article 2,

and

— are considered dangerous within the meaning of Article 5, 6 or 7.

3. The specific provisions set out:

— in Article 9 and defined in Annex IV,

— in Article 10 and defined in Annex V, and

— in Article 14

shall also apply to preparations which are not considered dangerous within the meaning of Articles 5, 6 or 7 but may nevertheless present a specific hazard.

4. Without prejudice to Directive 91/414/EEC, the articles on classification, packaging, labelling and safety data sheets of this Directive shall apply to plant protection products.

5. This Directive shall not apply to the following preparations in the finished state, intended for the final user:

(a) medicinal products for human or veterinary use, as defined in Directive 65/65/EEC [1];

(b) cosmetic products as defined in Directive 76/768/EEC [2];

(c) mixtures of substances which, in the form of waste, are covered by Directives 75/442/EEC [3] and 78/319/EEC [4];

(d) foodstuffs;

(e) animal feedingstuffs;

(f) preparations containing radioactive substances as defined by Directive 80/836/Euratom [5];

(g) medical devices which are invasive or used in direct physical contact with the human body in so far as Community measures lay down provisions for the classification and labelling of dangerous substances and preparations which ensure the same level of information provision and protection as this Directive.

6. This Directive shall not apply to:

— the carriage of dangerous preparations by rail, road, inland waterway, sea or air,

— preparations in transit which are under customs supervision, provided they do not undergo any treatment or processing.

Article 2

Definitions

1. For the purposes of this Directive:

(a) 'substances' means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

(b) 'preparations' means mixtures or solutions composed of two or more substances;

(c) 'polymer' means a substance consisting of molecules characterised by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition a 'monomer unit' means the reacted form of a monomer in a polymer;

[1] OJ L 22, 9.2.1965, p. 369. Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).
[2] OJ L 262, 27.9.1976, p. 169. Directive as last amended by Directive 97/18/EC (OJ L 114, 1.5.1997, p. 43).
[3] OJ L 194, 25.7.1975, p. 39. Directive as last amended by Commission Decision 96/350/EC (OJ L 135, 6.6.1996, p. 32).
[4] OJ L 84, 31.3.1978, p. 43.
[5] OJ L 246, 17.9.1980, p. 1. Directive as amended by Directive 84/467/Euratom (OJ L 265, 5.10.1984, p. 4).

(d) (……);

(e) 'placing on the market' means making available to third parties. Importation into the Community customs territory shall be deemed to be placing on the market for the purposes of this Directive;

(f) 'scientific research and development' means scientific experimentation, analysis or chemical research carried out under controlled conditions; it includes the determination of intrinsic properties, performance and efficacy as well as scientific investigation related to product development;

(g) 'process-orientated research and development' means the further development of a substance in the course of which pilot plant or production trials are used to test the fields of application of the substance;

(h) 'Einecs' means the European Inventory of Existing Commercial Chemical Substances. This inventory contains the definitive list of all chemical substances deemed to be on the Community market on 18 September 1981.

2. The following are 'dangerous' within the meaning of this Directive:

(a) explosive substances and preparations: solid, liquid, pasty or gelatinous substances and preparations which may also react exothermically without atmospheric oxygen thereby quickly evolving gases, and which, under defined test conditions, detonate, quickly deflagrate or upon heating explode when partially confined;

(b) oxidising substances and preparations: substances and preparations which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances;

(c) extremely flammable substances and preparations: liquid substances and preparations having an extremely low flash-point and a low boiling-point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure;

(d) highly flammable substances and preparations:

— substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or

— solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or

— liquid substances and preparations having a very low flash-point, or

— substances and preparations which, in contact with water or damp air, evolve extremely flammable gases in dangerous quantities;

(e) flammable substances and preparations: liquid substances and preparations having a low flash-point;

(f) very toxic substances and preparations: substances and preparations which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(g) toxic substances and preparations: substances and preparations which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(h) harmful substances and preparations: substances and preparations which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(i) corrosive substances and preparations: substances and preparations which may, on contact with living tissues, destroy them;

(j) irritant substances and preparations: non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation;

(k) sensitising substances and preparations: substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitisation such that on further exposure to the substance of preparation, characteristic adverse effects are produced;

(l) carcinogenic substances and preparations: substances or preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence;

(m) mutagenic substances and preparations: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence;

(n) substances and preparations which are toxic for reproduction: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce, or increase the incidence of, non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity;

(o) substances and preparations which are dangerous for the environment: substances and preparations which, were they to enter the environment, would or could present an immediate or delayed danger for one or more components of the environment.

Article 3

Determination of dangerous properties of preparations

1. The evaluation of the hazards of a preparation shall be based on the determination of:

— physico-chemical properties,

— properties affecting health,

— environmental properties.

These different properties shall be determined in accordance with the provisions laid down in Articles 5, 6 and 7.

Where laboratory tests are conducted, they shall be carried out on the preparation as placed on the market.

2. Where the determination of dangerous properties is carried out in accordance with Articles 5, 6 and 7, all dangerous substances within the meaning of Article 2 and in particular those which:

— are listed in Annex I to Directive 67/548/EEC,

— are listed in Elincs in accordance with Article 21 of Directive 67/548/EEC,

— are classified and labelled provisionally by the person responsible for the placing on the market in accordance with Article 6 of Directive 67/548/EEC,

— are classified and labelled in accordance with Article 7 of Directive 67/548/EEC and are not yet included in Elincs,

— are covered by Article 8 of Directive 67/548/EEC,

— are classified and labelled in accordance with Article 13 of Directive 67/548/EEC,

shall be taken into consideration in accordance with the provisions laid down in the method used.

3. For preparations covered by this Directive, dangerous substances as referred to in paragraph 2 which are classified as dangerous on the basis of their health and/or environmental effects, whether they are present as impurities or additives, shall be taken into consideration when their concentrations are equal to, or greater than, those defined in the following table unless lower values are given in Annex I to Directive 67/548/EEC, or in Part B of Annex II to this Directive or in Part B of Annex III thereto, unless otherwise specified in Annex V to this Directive.

Category of danger of the substance	Concentration to take into consideration for	
	gaseous preparations %vol/vol	other preparations %w/w
Very toxic	≥ 0,02	≥ 0,1
Toxic	≥ 0,02	≥ 0,1
Carcinogenic Category 1 or 2	≥ 0,02	≥ 0,1
Mutagenic Category 1 or 2	≥ 0,02	≥ 0,1
Toxic for reproduction Category 1 or 2	≥ 0,02	≥ 0,1
Harmful	≥ 0,2	≥ 1
Corrosive	≥ 0,02	≥ 1
Irritant	≥ 0,2	≥ 1
Sensitising	≥ 0,2	≥ 1
Carcinogenic Category 3	≥ 0,2	≥ 1

Category of danger of the substance	Concentration to take into consideration for	
	gaseous preparations %vol/vol	other preparations %w/w
Mutagenic Category 3	≥ 0,2	≥ 1
Toxic for reproduction Category 3	≥ 0,2	≥ 1
Dangerous for the environment N		≥ 0,1
Dangerous for the environment ozone	≥ 0,1	≥ 0,1
Dangerous for the environment		≥ 1

Article 4

General principles of classification and labelling

1. The classification of dangerous preparations according to the degree and specific nature of the hazards involved shall be based on the definitions of categories of danger laid down in Article 2.

2. The general principles of the classification and labelling of preparations shall be applied in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC, save where alternative criteria referred to in Article 5, 6, 7 or 10 and the relevant Annexes of this Directive are applied.

Article 5

Evaluation of the hazards deriving from physico-chemical properties

1. The hazards of a preparation deriving from its physico-chemical properties shall be assessed by determining, by means of the methods specified in Part A of Annex V to Directive 67/548/EEC, the physico-chemical properties of the preparation necessary for appropriate classification and labelling in accordance with the criteria laid down in Annex VI to that Directive.

2. By way of derogation from paragraph 1:

the determination of the explosive, oxidising, extremely flammable, highly flammable, or flammable properties is not necessary provided that:

— none of the constituents possesses such properties and that, on the basis of the information available to the manufacturer, the preparation is unlikely to present hazards of this kind,

— in the event of a change in the composition of a preparation of known composition, scientific evidence indicates that a reassessment of the hazards will not lead to a change in classification,

— preparations placed on the market in the form of aerosols satisfy the provisions of Article 9a of Directive 75/324/EEC [1].

3. For certain cases for which the methods laid down in Part A of Annex V to Directive 67/548/EEC are not appropriate, alternative calculation methods are laid down in Part B of Annex I to this Directive.

4. Certain exemptions from the application of the methods laid down in Part A of Annex V to Directive 67/548/EEC are referred to in Part A of Annex I to this Directive.

5. The hazards deriving from the physico-chemical properties of a preparation covered by Directive 91/414/EEC shall be assessed by determining the physico-chemical properties of the preparation necessary for appropriate classification in accordance with the criteria set out in Annex VI to Directive 67/548/EEC. These properties shall be determined by means of the methods laid down in Part A of Annex V to Directive 67/548/EEC unless other internationally recognised methods are acceptable in accordance with the provisions of Annexes II and III to Directive 91/414/EEC.

Article 6

Evaluation of health hazards

1. The health hazards of a preparation shall be assessed by one or more of the following procedures:

(a) by a conventional method described in Annex II;

(b) by determining the toxicological properties of the preparation necessary for appropriate classification in accordance with the criteria in Annex VI to Directive 67/548/EEC. These properties shall be determined by means of the methods laid down in Part B of Annex V to Directive 67/548/EEC, unless, in the case of plant protection products, other internationally recognised methods are acceptable in accordance with the provisions of Annexes II and III to Directive 91/414/EEC.

[1] OJ L 147, 9.6.1975, p. 40. Directive as last amended by Directive 94/1/EC (OJ L 23, 28.1.1994, p. 28).

2. Without prejudice to the requirements of Directive 91/414/EEC, only where it can be scientifically demonstrated by the person responsible for placing the preparation on the market that the toxicological properties of the preparation cannot correctly be determined by the method outlined in paragraph 1(a), or on the basis of existing test results on animals, the methods outlined in paragraph 1(b) may be used, provided they are justified or specifically authorised under Article 12 of Directive 86/609/EEC.

When a toxicological property is established by the methods outlined in paragraph 1(b) to obtain new data, the test shall be conducted in compliance with the principles of good laboratory practice provided for in Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances ([1]) and the provisions of Directive 86/609/EEC, in particular Articles 7 and 12 thereof.

Subject to the provisions of paragraph 3, where a toxicological property has been established on the basis of both the methods outlined in paragraphs 1(a) and (b), the results from the methods outlined in paragraph 1(b) shall be used for classifying the preparation, except in the case of carcinogenic, mutagenic or toxic effects for reproduction for which only the method outlined in 1(a) shall be used.

Any of the toxicological properities of the preparation which are not assessed by the method outlined in paragraph 1(b) shall be assessed in accordance with the method outlined in paragraph 1(a).

3. Furthermore, where it can be demonstrated:

— by epidemiological studies, by scientifically valid case studies as specified by Annex VI to Directive 67/548/EEC or by statistically backed experience, such as the assessment of data from poison information units or concerning occupational diseases, that toxicological effects on man differ from those suggested by the application of the methods outlined in paragraph 1, then the preparation shall be classified according to its effects on man,

— that, owing to effects such as potentiation, a conventional assessment would underestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation,

— that, owing to effects such as antagonism, a conventional assessment would overestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation.

4. For preparations of a known composition, with the exception of those covered by Directive 91/414/EEC, classified in accordance with paragraph 1(b), a new evaluation of health hazard by the methods outlined in either paragraph 1(a) or (b) shall be performed whenever:

— changes of composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer, in accordance with the following table:

Initial concentration range of the constituent	Permitted variation in initial concentration of the constituent
≤ 2,5 %	± 30 %
> 2,5 ≤ 10 %	± 20 %
> 10 ≤ 25 %	± 10 %
> 25 ≤ 100 %	± 5 %

— changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the meaning of the definitions set out in Article 2, are introduced by the manufacturer.

This new evaluation will apply unless there is valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.

Article 7

Evaluation of environmental hazards

1. The hazards of a preparation for the environment shall be assessed by one or more of the following procedures:

(a) by a conventional method described in Annex III to this Directive;

(b) by determining the hazardous properties of the preparation for the environment necessary for appropriate classification in accordance with the criteria set out in Annex VI to Directive 67/548/EEC. These properties shall be determined by means of the methods laid down in

([1]) OJ L 15, 17.1.1987, p. 29.

Part C of Annex V to Directive 67/548/EEC unless, in the case of plant protection products, other internationally recognised methods are acceptable in accordance with the provisions of Annexes II and III to Directive 91/414/EEC. Without prejudice to the testing requirements set out in Directive 91/414/EEC, the conditions for application of the test methods are described in Part C of Annex III to this Directive.

2. Where an ecotoxicological property is established by one of the methods outlined in paragraph 1(b) to obtain new data, the test shall be conducted in compliance with the principles of good laboratory practice provided for in Directive 87/18/EEC and with the provisions of Directive 86/609/EEC.

Where the environmental hazards have been assessed in compliance with both the procedures mentioned above, the results of the methods referred to in paragraph 1(b) shall be used for classifying the preparation.

3. For preparations of a known composition, with the exception of those covered by Directive 91/414/EEC, classified in accordance with the method outlined in paragraph 1(b), a new evaluation of environmental hazard either by the method outlined in paragraph 1(a) or that outlined in paragraph 1(b) shall be performed whenever:

— changes of composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer, in accordance with the following table:

Initial concentration range of the constituent	Permitted variation in initial concentration of the constituent
≤ 2,5 %	± 30 %
> 2,5 ≤ 10 %	± 20 %
> 10 ≤ 25 %	± 10 %
> 25 ≤ 100 %	± 5 %

— changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the meaning of the definitions set out in Article 2, are introduced by the manufacturer.

This new evaluation will apply unless there is valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.

Article 8

Obligations and duties of the Member States

1. Member States shall take all necessary measures to ensure that the preparations covered by this Directive cannot be placed on the market unless they comply with it.

2. In order to ensure compliance with this Directive, the authorities of the Member States may request information on the composition of the preparation and any other pertinent information from any person responsible for placing the preparation on the market.

3. Member States shall take all necessary measures to ensure that those responsible for placing the preparation on the market hold at the disposal of the authorities of the Member States:

— the data used for the classification and labelling of the preparation,

— any pertinent information relating to packaging requirements in accordance with Article 9(1.3), including the test certificate issued in accordance with Part A of Annex IX to Directive 67/548/EEC,

— the data used for establishing the safety data sheet, in accordance with Article 14.

4. Member States and the Commission shall exchange information concerning the name and full address of the national authority (authorities) responsible for communicating and exchanging information relating to the practical application of this Directive.

Article 9

Packaging

1. Member States shall take all necessary measures to ensure that:

1.1. preparations within the meaning of Article 1(2) and preparations covered by Annex IV pursuant to Article 1(3) cannot be placed on the market unless their packaging satisfies the following requirements:

— it shall be so designed and constructed that its contents cannot escape; this requirement shall not apply where special safety devices are prescribed,

— the materials constituting the packaging and fastenings must not be susceptible to adverse attack by the contents, or liable to form dangerous compounds with the contents,

— packaging and fastenings must be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling,

— containers fitted with replaceable fastening devices shall be so designed that the packaging can be refastened repeatedly without the contents escaping;

1.2. containers which contain preparations within the meaning of Article 1(2) and preparations covered by Annex IV pursuant to Article 1(3) offered or sold to the general public do not have:

— either a shape and/or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers, or

— a presentation and/or a designation used for foodstuffs or animal feedingstuffs or medicinal or cosmetic products.

1.3. containers which contain certain preparations offered or sold to the general public covered by Annex IV to this Directive:

— are fitted with child-resistant fastenings,

and/or

— carry a tactile warning of danger.

The devices must conform to the technical specifications given in Parts A and B of Annex IX to Directive 67/548/EEC.

2. The packaging of preparations shall be deemed to satisfy the requirements of paragraph 1.1, first, second and third indents, if it complies with the requirements for carriage of dangerous goods by rail, road, inland waterway, sea or air.

Article 10

Labelling

1.1. Member States shall take all necessary measures to ensure that:

(a) preparations within the meaning of Article 1(2) cannot be placed on the market unless the labelling on their packaging satisfies all the requirements of this Article and the specific provisions of Part A and B of Annex V;

(b) preparations within the meaning of Article 1(3) as defined in Parts B and C of Annex V cannot be placed on the market unless the labelling on their packaging satisfies the requirements of paragraphs 2.1 and 2.2 and the specific provisions of Parts B and C of Annex V.

1.2. With respect to plant protection products subject to Directive 91/414/EEC, the labelling requirements in accordance with this Directive shall be accompanied by the following wording:

'To avoid risks to man and the environment, comply with the instructions for use.'

This labelling shall be without prejudice to the information required in accordance with Article 16 of, and Annex V to, Directive 91/414/EEC.

2. The following information shall be clearly and indelibly marked on any package:

2.1. the trade name or designation of the preparation;

2.2. the name, full address and telephone number of the person established in the Community who is responsible for placing the preparation on the market, whether it be the manufacturer, the importer or the distributor;

2.3. the chemical name of the substance or substances present in the preparation in accordance with the following detailed rules:

2.3.1. for preparations classified T^+, T, X_n in accordance with Article 6, only the substances T^+, T, X_n present in concentrations equal to, or greater than, the lowest limit (limit X_n) for each of them laid down in Annex I to Directive 67/548/EEC or, failing that, Part B of Annex II to this Directive have to be taken into consideration;

2.3.2. for preparations classified C in accordance with Article 6, only C substances present in concentrations equal to, or greater than, the lowest limit (limit X_i) laid down in Annex I to Directive 67/548/EEC or, failing that, Part B of Annex II to this Directive have to be taken into consideration;

2.3.3. the name of the substances which have given rise to the classification of the preparation in one or more of the following danger categories:

— carcinogen category 1, 2 or 3,

— mutagen category 1, 2 or 3,

— toxic for reproduction category 1, 2 or 3,

— very toxic, toxic or harmful due to non-lethal effects after a single exposure,

— toxic or harmful due to severe effects after repeated or prolonged exposure,

— sensitising;

shall be mentioned on the label.

The chemical name shall be one of the designations listed in Annex I to Directive 67/548/EEC or an internationally recognised chemical nomenclature if no corresponding designation is yet listed in that Annex.

2.3.4. As a consequence of the above provisions the name of any substance which led to the classification of the preparation in the following danger categories:

— explosive,

— oxidising,

— extremely flammable,

— highly flammable,

— flammable,

— irritant,

— dangerous for the environment,

need not be mentioned on the label unless the substance has to be mentioned pursuant to paragraphs 2.3.1, 2.3.2 or 2.3.3.

2.3.5. As a general rule, a maximum of four chemical names shall suffice to identify the substances primarily responsible for the major health hazards which have given rise to the classification and the choice of the corresponding phrases referring to the risk involved. In some cases, more than four chemical names may be necessary.

2.4. **The danger symbol(s) and indication(s) of danger**

The danger symbols, where specified in this Directive, and indications of the dangers involved in the use of the preparation, shall be in accordance with the wording of Annexes II and VI to Directive 67/548/EEC and shall be applied in accordance with the evaluation of the hazards carried out in accordance with Annexes I, II and III to this Directive.

Where more than one danger symbol must be assigned to a preparation the obligation to apply the symbol:

— T shall make the symbols C and X optional unless otherwise specified in Annex I to Directive 67/548/EEC,

— C shall make the symbol X optional,

— E shall make the symbols F and O optional,

— X_n shall make the symbol X_i optional.

The symbol(s) shall be printed in black on an orange-yellow background.

2.5. **The risk phrases (R phrases)**

The indications concerning special risks (R phrases) shall comply with the wording in Annexes III and VI to Directive 67/548/EEC and shall be assigned in accordance with the results of the hazard evaluation carried out in accordance with Annexes I, II, and III to this Directive.

As a general rule, a maximum of six R phrases shall suffice to describe the risks; for this purpose, the combined phrases listed in Annex III to Directive 67/548/EEC shall be regarded as single phrases. However, if the preparation falls within more than one danger category, those standard phrases shall cover all the principal hazards associated with the preparation. In some cases more than six R phrases may be necessary.

The standard phrases 'extremely flammable' or 'highly flammable' need not be used where they describe an indication of danger used in accordance with 2.4.

2.6. **The safety advice (S phrases)**

The indications giving safety advice (S phrases) shall comply with the wording in Annex IV and with Annex VI to Directive 67/548/EEC and shall be assigned in accordance with the results of the hazard evaluation carried out in accordance with Annexes I, II and III to this Directive.

As a general rule, a maximum of six S phrases shall suffice to formulate the most appropriate safety advice; for this purpose the combined phrases listed in Annex IV to Directive 67/548/EEC shall be regarded as single phrases. However, in some cases more than six S phrases may be necessary.

Where it is physically impossible to include the advice on the label or package itself, the package shall be accompanied by safety advice on the use of the preparation.

2.7. The nominal quantity (nominal mass or nominal volume) of the contents in the case of preparations offered or sold to the general public.

3. For certain preparations classified as dangerous within the meaning of Article 7, by way of derogation from paragraphs 2.4, 2.5, and 2.6 of this Article, exemptions to certain provisions on environmental labelling or specific provisions in relation to environmental labelling may be determined in accordance with the procedure referred to in Article 20, where it can be demonstrated that there would be a reduction in the environmental impact. These exemptions or specific provisions are defined and laid down in Part A or B of Annex V.

4. If the contents of the package do not exceed 125 ml:

— in the case of preparations that are classified as highly flammable, oxidising, irritant, with the exception of those assigned R41, or dangerous for the environment and assigned the N symbol it shall not be necessary to indicate the R phrases or the S phrases,

— in the case of preparations that are classified as flammable or dangerous for the environment and not assigned the N symbol it shall be necessary to indicate the R phrases but it shall not be necessary to indicate the S phrases.

5. Without prejudice to Article 16(4) of Directive 91/414/EC, indications such as 'non-toxic', 'non-harmful', 'non-polluting', 'ecological' or any other statement indicating that the preparation is not dangerous or likely to lead to underestimation of the dangers of the preparation in question shall not appear on the packaging or labelling of any preparation subject to this Directive.

Article 11

Implementation of the labelling requirements

1. Where the particulars required by Article 10 appear on a label, that label shall be firmly affixed to one or more surfaces of the packaging so that those particulars can be read horizontally when the package is set down normally. The dimensions of the label are laid down in Annex VI to Directive 67/548/EEC and the label is intended solely for provision of the information required by this Directive and if necessary of any supplementary health or safety information.

2. A label shall not be required when the particulars are clearly shown on the package itself, as specified in paragraph 1.

3. The colour and presentation of the label — or, in the case of paragraph 2, of the package — shall be such that the danger symbol and its background stand out clearly from it.

4. The information required on the label under Article 10 shall stand out clearly from its background and shall be of such size and spacing as to be easily read.

Specific provisions regarding the presentation and format of this information shall be laid down in Annex VI to Directive 67/548/EEC.

5. Member States may make the placing on the market of preparations covered by this Directive within their territories subject to use of their official language or languages in respect of the labelling thereof.

6. For the purposes of this Directive, labelling requirements shall be deemed to be satisfied:

(a) in the case of an outer package containing one or more inner packages, if the outer package is labelled in accordance with international rules on the transport of dangerous goods and the inner package or packages are labelled in accordance with this Directive;

(b) in the case of a single package:

— if such a package is labelled in accordance with international rules on the transport of dangerous goods and with Article 10(2.1), (2.2), (2.3), (2.5) and (2.6); for preparations classified according to Article 7,

the provisions of Article 10(2.4) shall additionally apply with respect to the property in question when it has not been so identified on the label, or

— where appropriate, for particular types of packaging such as mobile gas cylinders, if the specific requirements referred to in Annex VI to Directive 67/548/EEC are complied with.

Where dangerous preparations do not leave the territory of a Member State, labelling may be permitted which complies with national rules instead of with international rules on the transport of dangerous goods.

Article 12

Exemptions from the labelling and packaging requirements

1. Articles 9, 10 and 11 shall not apply to explosives placed on the market with a view to obtaining an explosive or pyrotechnic effect.

2. For certain dangerous preparations within the meaning of Article 5, 6 or 7 defined in Annex VII which, in the form in which they are placed on the market, do not present any physico-chemical risk, or risk to health or to the environment, Articles 9, 10 and 11 shall not apply.

3. Member States may also:

(a) permit the labelling required by Article 10 to be applied in some other appropriate manner on packages which are either too small or otherwise unsuitable for labelling in accordance with Article 11(1) and (2);

(b) by way of derogation from Articles 10 and 11 permit the packaging of dangerous preparations which are classified as harmful, extremely flammable, highly flammable, flammable, irritant or oxidising to be unlabelled or to be labelled in some other way, if they contain such small quantities that there is no reason to fear any danger to persons handling such preparations or to other persons;

(c) by way of derogation from Articles 10 and 11, for preparations classified according to Article 7, permit the packaging of dangerous preparations to be unlabelled or labelled in some other way if they contain such small quantities that there is no reason to fear any dangers to the environment;

(d) by way of derogation from Articles 10 and 11 permit the packaging of dangerous preparations which are not mentioned in (b) or (c) above to be labelled in some other appropriate way, if the packages are too small for the labelling provided for in Articles 10 and 11 and there is no reason to fear any danger to persons handling such preparations or to other persons.

Where this paragraph is applied, the use of symbols, indications of danger, risk (R) phrases or safety (S) phrases different to those laid down in this Directive shall not be permitted.

4. If a Member State makes use of the options provided for in paragraph 3, it shall forthwith inform the Commission and Member States thereof. Where it is appropriate, measures shall be decided upon in the framework of Annex V and in accordance with the provisions of Article 20.

Article 13

Distance selling

Any advertisement for a preparation within the meaning of this Directive which enables a member of the general public to conclude a contract for purchase without first having sight of the label for that preparation must make mention of the type or types of hazard indicated on the label. This requirement is without prejudice to Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts [1].

Article 14

Safety data sheet

1. The safety data sheet information is principally intended for use by professional users and must enable them to take the necessary measures as regards the protection of health, safety and the environment at the place of work.

2.1. Member States shall take all the necessary measures to ensure that:

(a) the person responsible for placing on the market a preparation within the meaning of Article 1(2) provides a safety data sheet;

(b) the person responsible for placing on the market a preparation provides on request of a professional user a safety data sheet providing proportionate

[1] OJ L 144, 4.6.1997, p. 19.

information for preparations not classified as dangerous within the meaning of Articles 5, 6 and 7 but containing in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and ≥ 0,2 % by volume for gaseous preparations at least:

— one substance posing health or environmental hazards, or

— one substance for which there are Community workplace exposure limits.

2.2. The safety data sheet and its supply must comply with the provisions of Directive 91/155/EEC.

2.3. The necessary amendments required to adapt to technical progress Directive 91/155/EEC shall be adopted in accordance with the procedure laid down in Article 20 of this Directive.

In particular, the necessary amendments to take account of provisions in paragraph 2.1(b) shall be adopted before the date specified in Article 22(1).

2.4. The safety data sheet may be supplied on paper or electronically, provided that the addressee has the necessary means of receiving it.

Article 15

Confidentiality of chemical names

Where the person responsible for placing the preparation on the market can demonstrate that the disclosure on the label or safety data sheet of the chemical identity of a substance which is exclusively classified as:

— irritant with the exception of those assigned R41 or irritant in combination with one or more of the other properties mentioned in point 2.3.4 of Article 10, or

— harmful or harmful in combination with one or more of the properties mentioned in point 2.3.4 of Article 10 presenting acute lethal effects alone

will put at risk the confidential nature of his intellectual property, he may, in accordance with the provisions of Annex VI, be permitted to refer to that substance either by means of a name that identifies the most important functional chemical groups or by means of an alternative name. This procedure may not be applied where the substance concerned has been assigned a Community exposure limit.

Where the person responsible for placing a preparation on the market wishes to take advantage of confidentiality provisions, he shall make a request to the competent authority of the Member State in which the preparation is to be first placed on the market.

This request must be made in accordance with the provisions of Annex VI and must provide the information required in the form in Part A of that Annex. The competent authority may nevertheless request further information from the person responsible for placing the preparation on the market if such information appears necessary in order to evaluate the validity of the request.

The authority of the Member State receiving a request for confidentiality shall notify the applicant of its decision. The person responsible for placing the preparation on the market shall forward a copy of this decision to each of the Member States where he wishes to market the product.

Confidential information brought to the attention of the authorities of a Member State or of the Commission shall be treated in accordance with Article 19(4) of Directive 67/548/EEC.

Article 16

Rights of Member States regarding safety of workers

This Directive shall not affect the right of Member States to specify, in compliance with the Treaty, the requirements they deem necessary to ensure that workers are protected when using the dangerous preparations in question, provided that this does not mean that the classification, packaging, and labelling of dangerous preparations are modified in a way not provided for in this Directive.

Article 17

Bodies responsible for receiving information relating to health

Member States shall appoint the body or bodies responsible for receiving information, including chemical composition, relating to preparations placed on the market and considered dangerous on the basis of their health effects or on the basis of their physico-chemical effects.

Member States shall take the necessary steps to ensure that the appointed bodies provide all the requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used to meet any medical demand by formulating preventive and curative measures, in particular in case of emergency.

Member States shall ensure that the information is not used for other purposes.

Member States shall ensure that the appointed bodies have at their disposal all the information required from the manufacturers or persons responsible for marketing to carry out the tasks for which they are responsible.

Article 18

Free movement clause

Without prejudice to the provisions set out in other Community legislation, Member States may not prohibit, restrict or impede the placing on the market of preparations because of their classification, packaging, labelling or safety data sheets if such preparations comply with the provisions laid down in this Directive.

Article 19

Safeguard clause

1. Where a Member State has detailed evidence that a preparation, although satisfying the provisions of this Directive, constitutes a hazard for man or the environment on grounds relating to the provisions of this Directive, it may provisionally prohibit the placing on the market of that preparation or subject it to special conditions in its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2. In the case referred to in paragraph 1, the Commission shall consult the Member States as soon as possible.

3. The Commission shall take a decision in accordance with the procedure laid down in Article 20.

Article 20

Adaptation to technical progress

Amendments required to adapt the Annexes to this Directive to technical progress shall be adopted in accordance with the procedure laid down in Article 29(4)(a) of Directive 67/548/EEC.

The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 205(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If the Council has not acted within three months of the date of referral, the proposed measures shall be adopted by the Commission.

Article 21

Repeal of Directives

1. The Directives listed in Part A of Annex VIII are hereby repealed, without prejudice to the obligation of the Member States concerning the deadlines for transposition into national law and for application of the Directives indicated in Part B of Annex VIII.

2. The Directives listed in Part A of Annex VIII shall apply to Austria, Finland and Sweden subject to provisions laid down in Part C of that Annex and pursuant to the Treaty.

3. References to the repealed Directives shall constitute references to this Directive and should be read in accordance with the correlation table set out in Annex IX.

Article 22

Transposition

1. Member States shall adopt and publish before 30 July 2002 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

2. Member States shall apply the laws, regulations and administrative provisions referred to in paragraph 1:

(a) to preparations not within the scope of Directive 91/414/EEC or Directive 98/8/EC as from 30 July 2002; and

(b) to preparations within the scope of Directive 91/414/EEC or Directive 98/8/EC as from 30 July 2004.

3. When Member States adopt such measures, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The methods of making such reference shall be laid down by Member States.

Article 23

Entry into force

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 21(2) shall apply from 1 January 1999.

Article 24

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 31 May 1999.

For the European Parliament	*For the Council*
The President	*The President*
J. M. GIL-ROBLES	J. FISCHER

ANNEX I

METHODS FOR THE EVALUATION OF PHYSICO-CHEMICAL PROPERTIES OF PREPARATIONS IN ACCORDANCE WITH ARTICLE 5

PART A

Exemptions to test methods of Annex V — Part A to Directive 67/548/EEC

See 2.2.5 of Annex VI to Directive 67/548/EEC.

PART B

Alternative calculation methods

B.1. *Non-gaseous preparations*

1. Method for the determination of oxidising properties of preparations containing organic peroxides.

   See point 2.2.2.1 of Annex VI to Directive 67/548/EEC.

B.2. *Gaseous preparations*

1. Method for the determination of oxidising properties

   See 9.1.1.2 of Annex VI to Directive 67/548/EEC.

2. Method for the determination of flammability properties

   See 9.1.1.1 of Annex VI to Directive 67/548/EEC.

ANNEX II

METHODS FOR THE EVALUATION OF HEALTH HAZARDS OF PREPARATIONS IN ACCORDANCE WITH ARTICLE 6

Introduction

An assessment must be made for all the health effects corresponding to the health effects of substances contained in a preparation. This conventional method described in Parts A and B of this Annex is a calculation method which is applicable to all preparations and which takes into consideration all the health hazards of substances contained in the preparation. For that purpose the dangerous health effects have been subdivided into:

1. acute lethal effects;

2. non-lethal irreversible effects after a single exposure;

3. severe effects after repeated or prolonged exposure;

4. corrosive effects, irritant effects;

5. sensitising effects;

6. carcinogenic effects, mutagenic effects, toxic effects for reproduction.

The health effects of a preparation are to be assessed in accordance with Article 6(1)(a) by the conventional method described in parts A and B of this Annex using individual concentration limits.

(a) where the dangerous substances listed in Annex I to Directive 67/548/EEC are assigned concentration limits necessary for the application of the method of assessment described in part A of this Annex, these concentration limits must be used;

(b) where the dangerous substances do not appear in Annex I to Directive 67/548/EEC or appear there without the concentration limits necessary for the application of the method of evaluation described in part A of this Annex, the concentration limits must be assigned in accordance with the specifications in part B of this Annex.

The procedure for classification is set out in Part A of this Annex.

The classification of the substance(s) and the resulting classification of the preparation are expressed:

— either by a symbol and one or more risk phrases, or

— by categories (category 1, category 2 or category 3) also assigned risk phrases when substances and preparations are shown to be carcinogenic, mutagenic or toxic for reproduction. Therefore it is important to consider, in addition to the symbol, all the phrases denoting specific risks which are assigned to each substance under consideration.

The systematic assessment of all the dangerous health effects is expressed by means of concentration limits, expressed as a weight/weight percentage except for gaseous preparations where they are expressed as a volume/volume percentage and in conjunction with the classification of the substance.

Where they are not given in Annex I to Directive 67/548/EEC, the concentration limits to be taken into account for the application of this conventional method are those set out in Part B of this Annex.

PART A

Procedure for evaluation of health hazards

The evaluation proceeds stepwise as follows:

1. *The following preparations are to be classified as very toxic:*

1.1. owing to their acute lethal effects and assigned the symbol 'T^{+}', the indication of danger 'very toxic' and the risk phrases R26, R27 or R28;

1.1.1. preparations containing one or more substances classified as very toxic that produce such effects, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 1 in Part B of this Annex (Table I and I A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

1.1.2. preparations containing more than one substance classified as very toxic in lower individual concentrations than the limits specified under 1.1.1(a) or (b) if:

$$\sum \left(\frac{P_{T+}}{L_{T+}}\right) \geq 1$$

where:

P_{T+} = is the percentage by weight or by volume of each very toxic substance in the preparation,

L_{T+} = is the very toxic limit specified for each very toxic substance, expressed as a percentage by weight or by volume;

1.2. owing to their non-lethal irreversible effects after a single exposure and assigned the symbol 'T+', the indication of danger 'very toxic' and the risk phrase R39/route of exposure.

Preparations containing at least one dangerous substance that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 2 in Part B of this Annex (Table II and II A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

2. *The following preparations shall be classified as toxic:*

2.1. owing to their acute lethal effects and assigned the symbol 'T', the indication of danger 'toxic' and the risk phrases R23, R24 or R25;

2.1.1. preparations containing one or more substances classified as very toxic or toxic that produce such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 1 in Part B of this Annex (Table I and I A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

2.1.2. preparations containing more than one substance classified as very toxic or toxic in lower individual concentrations than the limits specified under 2.1.1(a) or (b) if:

$$\sum \left(\frac{P_{T+}}{L_T} + \frac{P_T}{L_T}\right) \geq 1$$

where:

P_{T+} = is the percentage by weight or by volume of each very toxic substance in the preparation,

P_T = is the percentage by weight or by volume of each toxic substance in the preparation,

L_T = is the respective toxic limit specified for each very toxic or toxic substance, expressed as a percentage by weight or by volume;

2.2. owing to their non-lethal irreversible effects after a single exposure and assigned the symbol 'T', the indication of danger 'toxic' and the risk phrase R39/route of exposure.

Preparations containing at least one dangerous substance classified as very toxic or toxic that produce such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 2 in Part B of this Annex (Table II and II A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

2.3. owing to their long-term effects and assigned the symbol 'T', the indication of danger 'toxic' and the risk phrase R48/route of exposure.

Preparations containing at least one dangerous substance that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 3 in Part B of this Annex (Table III and III A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

3. *The following preparations shall be classified as harmful:*

3.1. owing to their acute lethal effects and assigned the symbol 'X_n' and the indication of danger 'harmful' and the risk phrases R20, R21 or R22;

3.1.1. preparations containing one or more substances classified as very toxic, toxic or harmful and that produce such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 1 in Part B of this Annex (Table I and I A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

3.1.2. preparations containing more than one substance classified as very toxic, toxic or harmful in lower individual concentrations than the limits specified under 3.1.1(a) or (b) if:

$$\sum \left(\frac{P_{T+}}{L_{Xn}} + \frac{P_T}{L_{Xn}} + \frac{P_{Xn}}{L_{Xn}} \right) \geq 1$$

where:

P_{T+} = is the percentage by weight or by volume of each very toxic substance in the preparation,

P_T = is the percentage by weight or by volume of each toxic substance in the preparation,

P_{Xn} = is the percentage by weight or by volume of each harmful substance in the preparation,

L_{Xn} = is the respective harmful limit specified for each very toxic, toxic or harmful substance, expressed as percentage by weight or by volume;

3.2. owing to their acute effects to the lungs if swallowed and assigned the symbol 'X_n', and the indication of danger 'harmful' and the risk phrase R65.

Preparations classified as harmful according to the criteria specified in paragraph 3.2.3 of Annex VI to Directive 67/548/EEC. In applying the conventional method according to the above paragraph 3.1 no account shall be taken of the classification of a substance as R65;

3.3. owing to their non-lethal irreversible effects after a single exposure and assigned the symbol 'X_n', the indication of danger 'harmful' and the risk phrase R40/route of exposure.

Preparations containing at least one dangerous substance classified as very toxic, toxic or harmful that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 2 in Part B of this Annex (Table II and II A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

3.4. owing to their long-term effects and assigned the symbol 'X_n', the indication of danger 'harmful' and the risk phrase R48/route of exposure.

Preparations containing at least one dangerous substance classified as toxic or harmful that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 3 in Part B of this Annex (Table III and III A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

4. *The following preparations are to be classified as corrosive*

4.1. and assigned the symbol 'C', the indication of danger 'corrosive' and the risk phrase R35;

4.1.1. preparations containing one or more substances classified as corrosive to which is assigned the phrase R35 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

4.1.2. preparations containing more than one substance classified as corrosive to which is assigned phrase R35 in lower individual concentrations than the limits specified under 4.1.1(a) or (b) if:

$$\sum \left(\frac{P_{C,R35}}{L_{C,R35}} \right) \geq 1$$

where:

$P_{C,\,R35}$ = is the percentage by weight or by volume of each corrosive substance which is assigned phrase R35 in the preparation,

$L_{C,\,R35}$ = is the corrosive limit R35 specified for each corrosive substance to which is assigned phrase R35, expressed as a percentage by weight or by volume;

4.2. and assigned the symbol 'C', the indication of danger 'corrosive' and the risk phrase R34;

4.2.1. preparations containing one or more substances classified as corrosive to which is assigned the phrase R35 or R34 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

4.2.2. preparations containing more than one of the substances classified as corrosive to which is assigned the phrase R35 or R34 in lower individual concentrations than the limits specified under 4.2.1(a) or (b) if:

$$\sum \left(\frac{P_{C,R35}}{L_{C,R34}} + \frac{P_{C,R34}}{L_{C,R34}} \right) \geq 1$$

where:

$P_{C,\,R35}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,

$P_{C,\,R34}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,

$L_{C,\,R34}$ = is the respective corrosive limit R34 specified for each corrosive substance to which is assigned phrase R35 or R34, expressed as a percentage by weight or by volume.

5. *The following preparations are to be classified as irritants:*

5.1. liable to cause serious eye damage and assigned the symbol 'X_i', the indication of danger 'irritant' and the risk phrase R41;

5.1.1. preparations containing one or more substances classified as irritant to which is assigned phrase R41 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

5.1.2. preparations containing more than one of the substances classified as irritant and to which is assigned phrase R41, or classified as corrosive and to which is assigned phrase R35 or R34, in lower individual concentrations than the limits specified under 5.1.1(a) or (b) if:

$$\sum \left(\frac{P_{C,\,R35}}{L_{Xi,\,R41}} + \frac{P_{C,\,R34}}{L_{Xi,\,R41}} + \frac{P_{Xi,\,R41}}{L_{Xi,\,R41}} \right) \geq 1$$

where:

$P_{C,\,R35}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,

$P_{C,\,R34}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,

$P_{Xi,\,R41}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R41 in the preparation,

$L_{Xi,\,R41}$ = is the respective irritant limit R41 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R41, expressed as percentage by weight or by volume;

5.2. irritant to eyes and assigned the symbol 'X_i', the indication of danger 'irritant' and the risk phrase R36;

5.2.1. preparations containing one or more substances classified as corrosive to which is assigned phrase R35 or R34 or as irritant and to which is assigned phrase R41 or R36 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

5.2.2. preparations containing more than one substance classified as irritant to which is assigned phrase R41 or R36, or as corrosive and to which is assigned phrase R35 or R34, in lower individual concentrations than the limits specified under 5.2.1(a) or (b) if:

$$\sum \left(\frac{P_{C,\,R35}}{L_{Xi,\,R36}} + \frac{P_{C,\,R34}}{L_{Xi,\,R36}} + \frac{P_{Xi,\,R41}}{L_{Xi,\,R36}} + \frac{P_{Xi,\,R36}}{L_{Xi,\,R36}} \right) \geq 1$$

where:

$P_{C,\,R35}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,

$P_{C,\,R34}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,

$P_{Xi,\,R41}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R41 in the preparation,

$P_{Xi,\,R36}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R36 in the preparation,

$L_{Xi,\,R36}$ = is the respective irritant limit R36 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R41, or R36 expressed as percentage by weight or by volume;

5.3. irritant to skin and assigned the symbol 'X_i', the indication of danger 'irritant' and the risk phrase R38;

5.3.1. preparations containing one or more substances classified as irritant and to which is assigned phrase R38 or as corrosive and to which is assigned phrase R35 or R34 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

5.3.2. preparations containing more than one of the substances classified as irritant and to which is assigned phrase R38, or as corrosive and to which is assigned phrase R35 or R34 in lower individual concentrations than the limits specified under 5.3.1(a) or (b) if:

$$\sum \left(\frac{P_{C,\,R35}}{L_{Xi,\,R38}} + \frac{P_{C,\,R34}}{L_{Xi,\,R38}} + \frac{P_{Xi,\,R38}}{L_{Xi,\,R38}} \right) \geq 1$$

where:

$P_{C,\,R35}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,

$P_{C,\,R35}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,

$P_{Xi,\,R38}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R38 in the preparation,

$L_{Xi,\,R38}$ = is the respective irritant limit R38 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R38, expressed as percentage by weight or by volume;

5.4. irritant to respiratory system and assigned the symbol 'X_i', the indication of danger 'irritant' and the risk phrase R37;

5.4.1. preparations containing one or more substances classified as irritant and to which is assigned phrase R37 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV A) where the substance or the substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

5.4.2. preparations containing more than one substance classified as irritant and to which is assigned phrase R37 in lower individual concentrations than the limits specified under 5.4.1(a) or (b) if:

$$\sum \left(\frac{P_{Xi,\,R37}}{L_{Xi,\,R37}} \right) \geq 1$$

where:

$P_{Xi,\,R37}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R37 in the preparation,

$L_{Xi,\,R37}$ = is the irritant limit R37 specified for each irritant substance to which is assigned phrase R37, expressed as percentage by weight or by volume;

5.4.3. gaseous preparations containing more than one of the substances classified as irritant to which is assigned phrase R37 or as corrosive and to which is assigned phrase R35 or R34 in lower individual concentrations than the limits specified under 5.4.1(a) or (b) if:

$$\sum \left(\frac{P_{C,\,R35}}{L_{Xi,\,R37}} + \frac{P_{C,\,R34}}{L_{Xi,\,R37}} + \frac{P_{Xi,\,R37}}{L_{Xi,\,R37}} \right) \geq 1$$

where:

$P_{C,\,R35}$ = is the percentage by volume of each corrosive substance to which is assigned phrase R35 in the preparation,

$P_{C,\,R34}$ = is the percentage by volume of each corrosive substance to which is assigned phrase R34 in the preparation,

$P_{Xi,\,R37}$ = is the percentage by volume of each irritant substance to which is assigned phrase R37 in the preparation,

$L_{Xi,\,R37}$ = is the respective irritant limit R37 specified for each gaseous corrosive substance to which is assigned phrase R35 or R34 or gaseous irritant substance to which is assigned phrase R37, expressed as percentage by weight or by volume.

6. *The following preparations are to be classified as sensitising:*

6.1. by skin contact and assigned the symbol 'X_i', the indication of danger 'irritant' and the risk phrase R43.

Preparations containing at least one substance classified as sensitising and to which is assigned phrase R43 that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 5 in Part B of this Annex (Table V and V A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

6.2. by inhalation and assigned the symbol 'X_n', the indication of danger 'harmful' and the risk phrase R42.

Preparations containing at least one substance classified as sensitising to which is assigned phrase R42 that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 5 in Part B of this Annex (Table V and V A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

7. *The following preparations are to be classified as carcinogenic:*

7.1. those of category 1 or 2 which are assigned the symbol 'T' and the phrase R45 or R49.

Preparations containing at least one substance producing such effects, classified as carcinogenic and to which is assigned phrase R45 or R49 which denotes carcinogenic substances in category 1 and category 2, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

7.2. those of category 3 which are assigned the symbol 'X_n' and the phrase R40.

Preparations containing at least one substance producing such effects classified as carcinogenic and to which is assigned phrase R40 which denotes carcinogenic substances in category 3, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

8. *The following preparations are to be classified as mutagenic:*

8.1. those of category 1 or 2 which are assigned the symbol 'T' and the phrase R46.

Preparations containing at least one substance producing such effects, classified as mutagenic and to which is assigned phrase R46 which denotes mutagenic substances in category 1 and category 2, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

8.2. those of category 3 which are assigned the symbol 'X_n' and the phrase R40.

Preparations containing at least one substance, producing such effects, classified as mutagenic and to which is assigned phrase R40 which denotes mutagenic substances in category 3, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

9. *The following preparations are to be classified as toxic for reproduction:*

9.1. those of category 1 or 2 which are assigned the symbol 'T' and the phrase R60 (fertility).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R60 which denotes substances toxic for reproduction of category 1 and category 2, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

9.2. those of category 3 which are assigned the symbol 'X_n' and the phrase R62 (fertility).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R62 which denotes substances toxic for reproduction of category 3, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

9.3. those of category 1 or 2 which are assigned the symbol 'T' and the phrase R61 (development).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R61 which denotes substances toxic for reproduction of category 1 and category 2, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

9.4. those of category 3 which are assigned the symbol 'X_n' and the phrase R63 (development).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R63 which denotes substances toxic for reproduction of category 3, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

PART B

Concentration limits to be used in evaluation of health hazards

For each health effect, the first table (Tables I to VI) sets out the concentration limits (expressed as a weight/weight percentage) to be used for non-gaseous preparations and the second table (Tables I A to VI A) sets out the concentration limits (expressed as a volume/volume percentage) to be used for gaseous preparations. These concentration limits are used in the absence of specific concentration limits for the substance under consideration in Annex I to Directive 67/548/EEC.

1. *Acute lethal effects*

1.1. Non-gaseous preparations

The concentration limits fixed in Table I, expressed as a weight/weight percentage, determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

Table I

Classification of the substance	Classification of the preparation		
	T^+	T	X_n
T^+ with R26, R27, R28	concentration ≥ 7 %	1 % ≤ concentration < 7 %	0,1 % ≤ concentration < 1 %
T with R23, R24, R25		concentration ≥ 25 %	3 % ≤ concentration < 25 %
X_n with R20, R21, R22			concentration ≥ 25 %

The R phrases denoting risk are to be assigned to the preparation in accordance with the following criteria:

— the label shall include one or more of the abovementioned R phrases according to the classification used,

— in general, the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

1.2. Gaseous preparations

The concentration limits expressed as a volume/volume percentage in Table I A below determine the classification of the gaseous preparations in relation to the individual concentration of the gas(es) present whose classification is also shown.

Table I A

Classification of the substance (gas)	Classification of the gaseous preparation		
	T^+	T	X_n
T^+ with R26, R27, R28	concentration ≥ 1 %	0,2 % ≤ concentration < 1 %	0,02 % ≤ concentration < 0,2 %
T with R23, R24, R25		concentration ≥ 5 %	0,5 % ≤ concentration < 5 %
X_n with R20, R21, R22			concentration ≥ 5 %

The R phrases denoting risk shall be assigned to the preparation in accordance with the following criteria:

— the label shall include one or more of the abovementioned R phrases according to the classification used,

— in general, the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

2. *Non-lethal irreversible effects after a single exposure*

2.1. Non-gaseous preparations

For substances that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, R40/route of exposure), the individual concentration limits specified in Table II, expressed as a weight/weight percentage, determine, when appropriate, the classification of the preparation.

Table II

Classification of the substance	Classification of the preparation		
	T^+	T	X_n
T^+ with R39/route of exposure	concentration ≥ 10 % R39 (*) obligatory	1 % ≤ concentration < 10 % R39 (*) obligatory	0,1 % ≤ concentration < 1 % R40 (*) obligatory
T with R39/route of exposure		concentration ≥ 10 % R39 (*) obligatory	1 % ≤ concentration < 10 % R40 (*) obligatory
X_n with R40/route of exposure			concentration ≥ 10 % R40 (*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

2.2. Gaseous preparations

For gases that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, R40/route of exposure), the individual concentration limits specified in Table II A, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

Table II A

Classification of the substance (gas)	Classification of the gaseous preparation		
	T^+	T	X_n
T^+ with R39/route of exposure	concentration ≥ 1 % R39 (*) obligatory	0,2 % ≤ concentration < 1 % R39 (*) obligatory	0,02 % ≤ concentration < 0,2 % R40 (*) obligatory
T with R39/route of exposure		concentration ≥ 5 % R39 (*) obligatory	0,5 % ≤ concentration < 5 % R40 (*) obligatory
X_n with R40/route of exposure			concentration ≥ 5 % R40 (*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

3. *Severe effects after repeated or prolonged exposure*

3.1. Non-gaseous preparations

For substances that produce severe effects after repeated or prolonged exposure (R 48/route of exposure), the individual concentration limits specified in Table III, expressed as a weight/weight percentage, determine, when appropriate, the classification of the preparation.

Table III

Classification of the substance	Classification of the preparation	
	T	X_n
T with R48/route of exposure	concentration ≥ 10 % R48 (*) obligatory	1 % ≤ concentration < 10 % R48 (*) obligatory
X_n with R48/route of exposure		concentration ≥ 10 % R48 (*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

3.2. Gaseous preparations

For gases that produce severe effects after repeated or prolonged exposure (R48/route of exposure), the individual concentration limits specified in Table III A below, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

Table III A

Classification of the substance (gas)	Classification of the gaseous preparation	
	T	X_n
T with R48/route of exposure	concentration ≥ 5 % R48 (*) obligatory	0,5 % ≤ concentration < 5 % R48 (*) obligatory
X_n with R48/route of exposure		concentration ≥ 5 % R48 (*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

4. *Corrosive and irritant effects including serious damage to the eye*

4.1. Non-gaseous preparations

For substances that produce corrosive effects (R34, R35) or irritant effects (R36, R37, R38, R41), the individual concentration limits specified in Table IV, expressed as a weight/weight percentage, determine, when appropriate, the classification of the preparation.

Table IV

Classification of the substance	Classification of the preparation			
	C with R35	C with R34	X_i with R41	X_i with R36, R37, R38
C with R35	concentration ≥ 10 % R35 obligatory	5 % ≤ concentration < 10 % R34 obligatory	5 % (*)	1 % ≤ concentration < 5 % R36/38 obligatory
C with R34		concentration ≥ 10 % R34 obligatory	10 % (*)	5 % ≤ concentration < 10 % R36/38 obligatory

Classification of the substance	Classification of the preparation			
	C with R35	C with R34	X_i with R41	X_i with R36, R37, R38
X_i with R41			concentration ≥ 10% R41 obligatory	5% ≤ concentration < 10% R36 obligatory
X_i with R36, R37, R38				concentration ≥ 20% R36, R37, R38 are obligatory in the light of the concentration present if they apply to the substances under consideration

(*) According to the labelling guide (Annex VI to Directive 67/548/EEC), corrosive substances assigned risk phrases R35 or R34 must also be considered as being assigned phrase R41. Consequently, if the preparation contains corrosive substances with R35 or R34 below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant with R41 or irritant with R36.

4.2. Gaseous preparations

For gases that produce such effects (R34, R35 or R36, R37, R38, R41), the individual concentration limits specified in Table IV A below, expressed as a volume/volume percentage determine, when appropriate, the classification of the preparation.

Table IV A

Classification of the substance (gas)	Classification of the gaseous preparation			
	C with R35	C with R34	X_i with R41	X_i with R36, R37, R38
C with R35	concentration ≥ 1% R35 obligatory	0,2% ≤ concentration < 1% R34 obligatory	0,2% (*)	0,02% ≤ concentration < 0,2% R36/37/38 obligatory
C with R34		concentration ≥ 5% R34 obligatory	5% (*)	0,5% ≤ concentration < 5% R36/37/38 obligatory
X_i with R41			concentration ≥ 5% R41 obligatory	0,5% ≤ concentration < 5% R36 obligatory
X_i with R36, R37, R38				concentration ≥ 5% R36, R37, R38 obligatory as appropriate

(*) According to the labelling guide (Annex VI to Directive 67/548/EEC), corrosive substances assigned risk phrases R35 or R34 must also be considered as being assigned phrase R41. Consequently, if the preparation contains corrosive substances with R35 or R34 below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant with R41 or irritant with R36.

5. *Sensitising effects*

5.1. Non-gaseous preparations

Preparations that produce such effects are classified as sensitising and assigned:

— the symbol X_n and phrase R42 if this effect can be produced by inhalation,

— the symbol X_i and phrase R43 if this effect can be produced through contact with the skin.

The individual concentration limits specified in Table V, expressed as a weight/weight percentage, determine, when appropriate, the classification of the preparation.

Table V

Classification of the substance	Classification of the preparation	
	Sensitising with R42	Sensitising with R43
Sensitising with R42	concentration ≥ 1 % R42 obligatory	
Sensitising with R43		concentration ≥ 1 % R43 obligatory

5.2. Gaseous preparations

Gaseous preparations that produce such effects are classified as sensitising and assigned:

— the symbol X_n and phrase R42 if this effect can be produced by inhalation,

— the symbol X_i and phrase R43 if this effect can be produced through contact with the skin.

The individual concentration limits specified in Table V A below, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

Table V A

Classification of the substance (gas)	Classification of the gaseous preparation	
	Sensitising with R42	Sensitising with R43
Sensitising with R42	concentration ≥ 0,2 % R42 obligatory	
Sensitising with R43		concentration ≥ 0,2 % R43 obligatory

6. *Carcinogenic/mutagenic/toxic effects for reproduction*

6.1. Non-gaseous preparations

For substances which produce such effects, the concentration limits laid down in Table VI, expressed as a weight/weight percentage, shall determine, where appropriate, the classification of the preparation. The following symbol and risk phrases are assigned:

Carcinogenic categories 1 and 2:	T; R45 or R49
Carcinogenic category 3:	X_n; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	X_n; R40
Toxic for reproduction fertility categories 1 and 2:	T; R60
Toxic for reproduction development categories 1 and 2:	T; R61
Toxic for reproduction fertility category 3:	X_n; R62
Toxic for reproduction development category 3:	X_n; R63

Table VI

Classification of the substance	Classification of the preparation	
	Categories 1 and 2	Category 3
carcinogenic substances of category 1 or 2 with R45 or R49	concentration ≥ 0,1 % carcinogenic R45, R49 obligatory as appropriate	
carcinogenic substances of category 3 with R40		concentration ≥ 1 % carcinogenic R40 obligatory
mutagenic substances of category 1 or 2 with R46	concentration ≥ 0,1 % mutagenic R46 obligatory	
mutagenic substances of category 3 with R40		concentration ≥ 1 % mutagenic R40 obligatory
substances 'toxic for reproduction' of category 1 or 2 with R60 (fertility)	concentration ≥ 0,5 % toxic for reproduction (fertility) R60 obligatory	
substances 'toxic for reproduction' of category 3 with R62 (fertility)		concentration ≥ 5 % toxic for reproduction (fertility) R62 obligatory
substances 'toxic for reproduction' of category 1 or 2 with R61 (development)	concentration ≥ 0,5 % toxic for reproduction (development) R61 obligatory	
substances 'toxic for reproduction' of category 3 with R63 (Development)		concentration ≥ 5 % toxic for reproduction (development) R63 obligatory

6.2. Gaseous preparations

For gases which produce such effects, the concentration limits laid down in Table VI A, expressed as a volume/volume percentage, shall determine, where appropriate, the classification of the preparation. The following symbol and risk phrases are assigned:

Carcinogenic categories 1 and 2:	T; R45 or R49
Carcinogenic category 3:	X_n; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	X_n; R40
Toxic for reproduction fertility categories 1 and 2:	T; R60
Toxic for reproduction development categories 1 and 2:	T; R61
Toxic for reproduction fertility category 3:	X_n; R62
Toxic for reproduction development category 3:	X_n; R63

Table VI A

Classification of the substance (gas)	Classification of the gaseous preparation	
	Categories 1 and 2	Category 3
carcinogenic substances of category 1 or 2 with R45 or R49	concentration ≥ 0,1 % carcinogenic R45, R49 obligatory as appropriate	
carcinogenic substances of category 3 with R40		concentration ≥ 1 % carcinogenic R40 obligatory
mutagenic substances of category 1 or 2 with R46	concentration ≥ 0,1 % mutagenic R46 obligatory	
mutagenic substances of category 3 with R40		concentration ≥ 1 % mutagenic R40 obligatory
substances 'toxic for reproduction' of category 1 or 2 with R60 (fertility)	concentration ≥ 0,2 % toxic for reproduction (fertility) R60 obligatory	
substances 'toxic for reproduction' of category 3 with R62 (fertility)		concentration ≥ 1 % toxic for reproduction (fertility) R62 obligatory
substances 'toxic for reproduction' of category 1 or 2 with R61 (development)	concentration ≥ 0,2 % toxic for reproduction (development) R61 obligatory	
substances 'toxic for reproduction' of category 3 with R63 (development)		concentration ≥ 1 % toxic for reproduction (development) R63 obligatory

ANNEX III

METHODS FOR THE EVALUATION OF THE ENVIRONMENTAL HAZARDS OF PREPARATIONS IN ACCORDANCE WITH ARTICLE 7

Introduction

The systematic assessment of all the dangerous properties for the environment is expressed by means of concentration limits, expressed as a weight/weight percentage except for gaseous preparations where they are expressed as a volume/volume percentage and in conjunction with the classification of a substance.

Part A gives the calculation procedure according to Article 7(1)(a) and gives the R phrases to be assigned to the classification of the preparation.

Part B gives the concentration limits to be used when applying the conventional method and relevant symbols and R phrases for classification.

In accordance with Article 7(1)(a) the environmental hazards of a preparation shall be assessed by the conventional method described in parts A and B of this Annex, using individual concentration limits.

(a) Where the dangerous substances listed in Annex 1 to Directive 67/548/EEC are assigned concentration limits necessary for the application of the method of assessment described in Part A of this Annex, these concentration limits must be used.

(b) Where the dangerous substances do not appear in Annex I to Directive 67/548/EEC or appear there without the concentration limits necessary for the application of the method of evaluation described in Part A of this Annex, the concentration limits shall be assigned in accordance with the specification in Part B of this Annex.

Part C gives the test methods for the evaluation of the hazards for the aquatic environment.

PART A

Procedure for the evaluation of environmental hazards

(a) *Aquatic environment*

I. Conventional method for the evaluation of hazards to the aquatic environment

The conventional method for the evaluation of hazards to the aquatic environment takes into account all the hazards that a substance may entail for this medium according to the following specifications.

The following preparations are to be classified as dangerous for the environment:

1. and assigned the symbol 'N', the indication of danger 'dangerous for the environment' and the risk phrases R50 and R53 (R50–53):

1.1. preparations containing one or more substances classified as dangerous to the environment and to which is assigned phrases R50–53 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

1.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrases R50–53 in lower individual concentrations than the limits specified under I.1.1(a) or (b) if:

$$\sum \left(\frac{P_{N,\,R50-53}}{L_{N,\,R50-53}} \right) \geq 1$$

where:

$P_{N,\,R50-53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50–53 in the preparation,

$L_{N,\,R50-53}$ = is the limit R50-53 for each substance dangerous for the environment to which is assigned the phrases R50–53, expressed as percentage by weight

2. and assigned the symbol 'N', the indication of danger 'dangerous for the environment' and the risk phrases R51 and R53 (R51–53) unless the preparation is already classified according to I.1 above;

2.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrases R50–53 or R51–53 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

2.2. preparations containing more than one of the substances classified as dangerous for the environment and to which is assigned phrases R50–53 or R51–53 in lower individual concentrations than the limits specified under I.2. (a) or (b) if:

$$\sum \left(\frac{P_{N,\,R50-53}}{L_{N,\,R51-53}} + \frac{P_{N,\,R51-53}}{L_{N,\,R51-53}} \right) \geq 1$$

where:

$P_{N,\,R50-53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50–53 in the preparation,

$P_{N,\,R51-53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R51–53 in the preparation,

$L_{N,\,R51-53}$ = is the respective limit R51–53 for each substance dangerous for the environment to which is assigned phrases R50–53 or R51–53, expressed as percentage by weight

3. and assigned the risk phrases R52 and R53 (R52–53) unless the preparation is already classified according to I.1 or I.2 above;

3.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrases R50–53 or R51–53 or R52–53 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

3.2. preparations containing more than one of the substances classified as dangerous for the environment and to which is assigned phrases R51–53 or R50–53 or R52–53 in lower individual concentrations than the limits specified under I.3.1(a) or (b) if:

$$\sum \left(\frac{P_{N,\,R50-53}}{L_{R52-53}} + \frac{P_{N,\,R51-53}}{L_{R52-53}} + \frac{P_{R52-53}}{L_{R52-53}} \right) \geq 1$$

where:

$P_{N,\,R50-53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50–53 in the preparation,

$P_{N,\ R51—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R51–53 in the preparation,

$P_{R52—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R52–53 in the preparation,

$L_{R52—53}$ = is the respective limit R52–53 for each substance dangerous for the environment to which is assigned phrases R50–53 or R51–53 or R52–53, expressed as percentage by weight;

4. and assigned the symbol 'N', the indication of danger 'dangerous for the environment' and the risk phrase R50 unless the preparation is already classified according to I.1 above:

4.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrase R50 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 2) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

4.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R50 in lower individual concentrations than the limits specified under I.4.1(a) or (b) if:

$$\sum \left(\frac{P_{N,\ R50}}{L_{N,\ R50}} \right) \geq 1$$

where:

$P_{N,\ R50}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R50 in the preparation,

$L_{N,\ R50}$ = is the limit R50 for each substance dangerous for the environment to which is assigned phrase R50, expressed as percentage by weight.

4.3. preparations containing one or more than one of the substances classified as dangerous for the environment and to which is assigned phrase R50 not meeting the criteria under I.4.1 or I.4.2 and containing one or more than one substance classified as dangerous for the environment and to which is assigned phrases R50–53 if:

$$\sum \left(\frac{P_{N,\ R50}}{L_{N,\ R50}} + \frac{P_{N,\ R50—53}}{L_{N,\ R50}} \right) \geq 1$$

where:

$P_{N,\ R50}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R50 in the preparation,

$P_{N,\ R50—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50–53 in the preparation,

$L_{N,\ R50}$ = is the perspective limit R50 for each substance dangerous for the environment to which is assigned phrases R50 or R50–53, expressed as percentage by weight;

5. and assigned the risk phrase R52 unless the preparation is already classified according to I.1, I.2, I.3, or I.4 above:

5.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrase R52 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 3) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

5.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R52 in lower individual concentrations than the limits specified under I.5.1 (a) or (b) if:

$$\sum \left(\frac{P_{R52}}{L_{R52}} \right) \geq 1$$

where:

P_{R52} = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R52 in the preparation,

L_{R52} = is the limit R52 for each substance dangerous for the environment to which is assigned phrase R52, expressed as percentage by weight;

6. and assigned the risk phrase R53 unless the preparation is already classified according to I.1, I.2, or I.3 above:

6.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrase R53 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 4) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

6.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R 53 in lower individual concentrations than the limits specified under I.6.1(a) or (b) if:

$$\sum \left(\frac{P_{R53}}{L_{R53}} \right) \geq 1$$

where:

P_{R53} = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R53 in the preparation,

L_{R53} = is the limit R53 for each substance dangerous for the environment to which is assigned phrase R53, expressed as percentage by weight;

6.3. preparations containing one or more than one of the substances classified as dangerous for the environment and to which is assigned phrase R53 not meeting the criteria under I.6.2 and containing one or more than one substance classified as dangerous for the environment and to which is assigned phrases R50–53 or R51–53 or R52–53 if:

$$\sum \left(\frac{P_{R53}}{L_{R53}} + \frac{P_{N,\,R50—53}}{L_{R53}} + \frac{P_{N,\,R51—53}}{L_{R53}} + \frac{P_{R52—53}}{L_{R53}} \right) \geq 1$$

where:

P_{R53} = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R53 in the preparation,

$P_{N,\,R50—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R50–53 in the preparation,

$P_{N,\,R51—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R51–53 in the preparation,

$P_{R52—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R52–53 in the preparation,

L_{R53} = is the respective limit R53 for each substance dangerous for the environment to which is assigned phrase R53 or R50–53 or R51–53 or R52–53, expressed as percentage by weight.

(b) *Non-aquatic environment*

(1) OZONE LAYER

I. Conventional method for the evaluation of preparations dangerous for the ozone layer

The following preparations are to classified as dangerous for the environment:

1. and assigned the symbol 'N', the indication of danger 'dangerous for the environment' and the risk phrase R59;

1.1. preparations containing one or more substances classified as dangerous to the environment and to which is assigned the symbol 'N' and the risk phrase R59 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 5) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

2. and assigned the risk phrase R59:

2.1. preparations containing one or more substances classified as dangerous to the environment and to which is assigned R59 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 5) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

(2) TERRESTRIAL ENVIRONMENT

I. Evaluation of preparations dangerous for the terrestrial environment

Classification of preparations using the risk phrases below will follow after the detailed criteria for use of the phrases have been incorporated in Annex VI to Directive 67/548/EEC.

R54 Toxic to flora

R55 Toxic to fauna

R56 Toxic to soil organisms

R57 Toxic to bees

R58 May cause long-term adverse effects in the environment.

PART B

Concentration limits to be used for the evaluation of environmental hazards

I. *For the aquatic environment*

The concentration limits fixed in the following tables, expressed as a weight/weight percentage, determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

Table 1

Acute aquatic toxicity and long-term adverse effects

Classification of the substance	Classification of the preparation		
	N, R50—53	N, R51—53	R52—53
N, R50—53	$C_n \geq 25\%$	$2{,}5\% \leq C_n < 25\%$	$0{,}25\% \leq C_n < 2{,}5\%$
N, R51—53		$C_n \geq 25\%$	$2{,}5\% \leq C_n < 25\%$
R52—53			$C_n \geq 25\%$

Table 2

Acute aquatic toxicity

Classification of the substance	Classification of the preparation N, R50
N, R50	$C_n \geq 25\%$
N, R50—53	$C_n \geq 25\%$

Table 3

Aquatic toxicity

Classification of the substance	Classification of the preparation R52 R52
R52	$C_n \geq 25\%$

Table 4

Long-term adverse effects

Classification of the substance	Classification of the preparation R53 R53
R53	$C_n \geq 25\%$
N, R50—53	$C_n \geq 25\%$
N, R51—53	$C_n \geq 25\%$
R52—53	$C_n \geq 25\%$

II. *For the non-aquatic environment*

The concentration limits fixed in the following tables, expressed as weight/weight percentage or, for gaseous preparations as a volume/volume percentage, determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

Table 5

Dangerous for the ozone layer

Classification of the substance	Classification of preparation N, R59
N with R59	C ≥ 0,1 %

Classification of the substance	Classification of preparation R59
R59	C ≥ 0,1 %

PART C

Test methods for the evaluation of the hazards for the aquatic environment

Normally, the classification of a preparation is made on the basis of the conventional method. However, for the determination of the acute aquatic toxicity, there may be cases for which it is appropriate to carry out tests on the preparation.

The result of these tests on the preparation may only modify the classification concerning acute aquatic toxicity which would have been obtained by the application of the conventional method.

If such tests are chosen by the person responsible for the placing on the market, it must be ensured that the quality criteria of the test methods in Part C of Annex V to Directive 67/548/EEC have been complied with.

Furthermore, the tests are to be carried out on all three species in conformity with the criteria of Annex VI to Directive 67/548/EEC (algae, daphnia and fish), unless the highest hazard classification relating to acute aquatic toxicity has been assigned to the preparation after testing on one of the species or a test result was already available before this Directive entered into force.

ANNEX IV

SPECIAL PROVISIONS FOR CONTAINERS CONTAINING PREPARATIONS OFFERED OR SOLD TO THE GENERAL PUBLIC

PART A

Containers to be fitted with child-resistant fastenings

1. Containers of whatever capacity, containing preparations offered or sold to the general public and labelled as very toxic, toxic or corrosive in accordance with Article 10 and under the conditions laid down in Article 6 of this Directive, are to fitted with child-resistant fastenings.

2. Containers of whatever capacity containing preparations presenting an aspiration hazard (X_n, R65) and classified and labelled according to paragraph 3.2.3 of Annex VI to Directive 67/548/EEC with the exception of preparations placed on the market in the form of aerosols or in a container fitted with a sealed spray attachment.

3. Containers of whatever capacity, having at least one of the substances mentioned below present in a concentration equal to or greater than the maximum individual concentration specified,

No	Identification of the substance			Concentration limit
	CAS-Reg No	Name	Einecs No	
1	67-56-1	Methanol	2006596	≥ 3 %
2	75-09-2	Dichloromethane	2008389	≥ 1 %

which are offered or sold to the general public are to be fitted with child-resistant fastenings.

PART B

Containers to be fitted with a tactile warning of danger

Containers of whatever capacity, containing preparations offered or sold to the general public and labelled as very toxic, toxic, corrosive, harmful, extremely flammable or highly flammable in accordance with Article 10 and under the conditions laid down in Articles 5 and 6 of this Directive, are to carry a tactile warning of danger.

This provision does not apply to aerosols classified and labelled only as extremely flammable or highly flammable.

ANNEX V

SPECIAL PROVISIONS CONCERNING THE LABELLING OF CERTAIN PREPARATIONS

A. For preparations classified as dangerous within the meaning of Articles 5, 6 and 7

1. *Preparations sold to the general public*

1.1. The labels on packages containing such preparations, in addition to the specific safety advice, must bear the relevant safety advice S1, S2, S45 or S46 in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC.

1.2. When such preparations are classified as very toxic (T^+), toxic (T) or corrosive (C) and where it is physically impossible to give such information on the package itself, packages containing such preparations must be accompanied by precise and easily understandable instructions for use including, where appropriate, instructions for the destruction of the empty package.

2. *Preparations intended for use by spraying*

The package label containing such preparations must compulsorily bear the safety advice S23 accompanied by safety advice S38 or S51 assigned to it in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC.

3. *Preparations containing a substance assigned phrase R33: Danger of cumulative effects*

When a preparation contains at least one substance assigned the phrase R33, the label of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the concentration of this substance present in the preparation is equal to or higher than 1%, unless different values are set in Annex I to Directive 67/548/EEC.

4. *Preparations containing a substance assigned phrase R64: May cause harm to breastfed babies*

When a preparation contains at least one substance assigned phrase R64, the label of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the concentration of this substance present in the preparation is equal to or higher than 1%, unless different values are set in Annex I to Directive 67/548/EEC.

B. For preparations irrespective of their classification within the meaning of Articles 5, 6 and 7

1. *Preparations containing lead*

1.1. Paint and varnishes

Labels of packages of paints and varnishes containing lead in quantities exceeding 0,15% (expressed as weight of metal) of the total weight of the preparation, as determined in accordance with ISO standard 6503/1984, must show the following particulars:

'Contains lead. Should not be used on surfaces liable to be chewed or sucked by children'.

In the case of packages the contents of which are less than 125 millilitres, the particulars may be as follows:

'Warning! Contains lead'.

2. *Preparations containing cyanoacrylates*

2.1. Adhesives

The immediate packaging of adhesives based on cyanoacrylate must bear the following inscriptions:

'Cyanoacrylate

Danger

Bonds skin and eyes in seconds

Keep out of the reach of children'.

Appropriate advice on safety must accompany the package.

3. *Preparations containing isocyanates*

The package labels of preparations containing isocyanates (as monomers, oligomers, prepolymers, etc., or as mixtures thereof) must bear the following inscriptions:

'Contains isocyanates.

See information supplied by the manufacturer.'

4. *Preparations containing epoxy constituents with an average molecular weight ≤ 700*

The package labels of preparations containing epoxy constituents with an average molecular weight ≤ 700 must bear the following inscriptions:

'Contains epoxy constituents.

See information supplied by the manufacturer.'

5. *Preparations sold to the general public which contain active chlorine*

The packaging of preparations containing more than 1 % of active chlorine must bear the following particular inscriptions:

'Warning! Do not use together with other products. May release dangerous gases (chlorine).'

6. *Preparations containing cadmium (alloys) and intended to be used for brazing or soldering*

The packaging of the abovementioned preparations must bear the following inscription printed in clearly legible and indelible characters:

'Warning! Contains cadmium.

Dangerous fumes are formed during use.

See information supplied by the manufacturer.

Comply with the safety instructions.'

7. *Preparations available as aerosols*

Without prejudice to the provisions of this Directive, preparations available as aerosols are also subject to the labelling provisions in accordance with points 2.2 and 2.3 of the Annex to Directive 75/324/EEC as last amended by Directive 94/1/EC.

8. *Preparations containing substances not yet tested completely*

Where a preparation contains at least one substance which, in accordance with Article 13.3 of Directive 67/548/EEC, bears the inscription 'Warning — substance not yet tested completely', the label of the preparation must bear the inscription 'Warning — this preparation contains a substance not yet tested completely' if this substance is present in a concentration ≥ 1 %.

9. *Preparations not classified as sensitising but containing at least one sensitising substance*

The packaging of preparations containing at least one substance classified as sensitising and being present in a concentration equal to or greater than 0,1 % or in a concentration equal to or greater than that specified under a specific note for the substance in Annex I to Directive 67/548/EEC must bear the inscription:

'Contains (name of sensitising substance). May produce an allergic reaction.'

10. *Liquid preparations containing halogenated hydrocarbons*

For liquid preparations which show no flashpoint or a flashpoint higher than 55 °C and contain a halogenated hydrocarbon and more than 5 % flammable or highly flammable substances, the packaging must bear the following inscription as appropriate:

'Can become highly flammable in use' or 'Can become flammable in use'.

C. **For preparations not classified within the meaning of Articles 5, 6 and 7 but containing at least one dangerous substance**

1. *Preparations not intended for the general public*

The label on the packaging of the preparations referred to in Article 14.2.1(b) must bear the following inscription:

'Safety data sheet available for professional user on request'.

ANNEX VI

CONFIDENTIALITY FOR THE CHEMICAL IDENTITY OF A SUBSTANCE

PART A

Information to be communicated in the request for confidentiality

Introductory notes

A. Article 15 indicates the conditions in which the person responsible for placing a preparation on the market may avail himself of the confidentiality.

B. To avoid multiple requests for confidentiality relating to the same substance used in different preparations, a single request for confidentiality may suffice if a certain number of preparations have:

— the same dangerous constituents present in the same concentration range,

— the same classification and labelling,

— the same expected uses.

A single alternative denomination must be used to mask the chemical identity of the same substance in the preparations concerned. Furthermore, the request for confidentiality must contain all information indicated in the following request, without forgetting the name or the trade name of each preparation.

C. The alternative designation used on the label must be the same as that given under heading 2 'Composition/information on ingredients' of the Annex to Directive 91/155/EEC as last amended by Directive 93/112/EEC.

This implies that the alternative designation used will contain enough information about the substance to ensure risk-free handling.

D. In making the request to use an alternative designation the person responsible for placing on the market must take into account the need to provide enough information for necessary health and safety precautions to be taken in the workplace and to ensure that risks from handling the preparation can be minimised.

Request for confidentiality

In accordance with Article 15 the request for confidentiality must obligatorily contain the following information:

1. Name and full address (including telephone number) of the person established in the Community who is responsible for placing the preparation on the market (manufacturer, importer or distributor).

2. Precise identification of the substance(s) for which confidentiality is proposed and the alternative designation.

CAS No	Einecs No	Chemical name according to international nomenclature and classification (Annex I to Council Directive 67/548/EEC or provisional classification)	Alternative designation
(a)			
(b)			
(c)			

NB: Where substances are classified provisionally, accompanying information (bibliographical references) should be provided as evidence that the provisional classification takes account of all existing pertinent information available on the properties of the substance.

3. Justification for confidentiality (probability — plausibility).

4. Designation(s) or commercial name(s) of the preparation(s).

5. Is the designation or commercial name the same for all the Community?

YES ☐ NO ☐

If no, specify the designation(s) or commercial name(s) used in the different Member States:

Austria:

Belgium:

Denmark:

Germany:

Greece:

Finland:

France:

Spain:

Sweden:

Ireland:

Italy:

Luxembourg:

Netherlands:

Portugal:

United Kingdom:

6. Composition of the preparation(s) defined in point 2 of the Annex to Directive 91/155/EEC as last amended by Directive 93/112/EEC.

7. Classification of the preparation(s) according to Article 6 of this Directive.

8. Labelling of the preparation(s) according to Article 10 of this Directive.

9. Intended uses for the preparation(s).

10. Safety data sheet(s) conforming to Directive 91/155/EEC as last amended by Directive 93/112/EEC.

PART B

Lexicon guide for establishing the alternative designations (generic names)

1. **Introductory note**

The lexicon guide is based on the procedure for the classification of dangerous substances (division of substances into families) which appears in Annex I to Directive 67/548/EEC.

Alternative designations to those based on this guide may be used. However, in all cases the names chosen must provide enough information to ensure the preparation can be handled without risk and that necessary health and safety precautions can be taken in the workplace.

The families are defined in the following manner:

— inorganic or organic substances whose properties are identified by having a common chemical element as their chief characteristic. The family name is derived from the name of the chemical element. These families are identified as in Annex I by the atomic number of the chemical element (001 to 103),

— organic substances whose properties are identified by having a common functional group as their chief characteristics.

The family name is derived from the functional group name.

These families are identified by the conventional number found in Annex I (601—650).

Sub-families bringing together substances with a common specific character have been added in certain cases.

2. **Establishing the generic name**

General principles

For the purposes of establishing the generic name, the following general approach, involving two successive stages, is adopted:

(i) identification of the functional groups and chemical elements present in the molecule;

(ii) determination of the extent to which account should be taken of the most important functional groups and chemical elements.

The identified functional groups and elements taken into account are the names of the families and sub-families set out in point 3 in the form of a non-restrictive list.

3. **Division of substances into families and sub-families**

Family No Annex I to Directive 67/548/EEC	Families / Sub-families
001	Hydrogen compounds Hydrides
002	Helium compounds
003	Lithium compounds
004	Beryllium compounds
005	Boron compounds Boranes Borates
006	Carbon compounds Carbamates Inorganic carbon compounds Salts of hydrogen cyanide Urea and derivatives
007	Nitrogen compounds Quaternary ammonium compounds Acid nitrogen compounds Nitrates Nitrites
008	Oxygen compounds
009	Fluorine compounds Inorganic fluorides

Family No Annex I to Directive 67/548/EEC	Families / Sub-families
010	Neon compounds
011	Sodium compounds
012	Magnesium compounds Organometallic magnesium derivatives
013	Aluminium compounds Organometallic aluminium derivatives
014	Silicon compounds Silicones Silicates
015	Phosphorus compounds Acid phosphorus compounds Phosphonium compounds Phosphoric esters Phosphates Phosphites Phosphoramides and derivatives
016	Sulphur compounds Acid sulphur compounds Mercaptans Sulphates Sulphites
017	Chlorine compounds Chlorates Perchlorates
018	Argon compounds
019	Potassium compounds
020	Calcium compounds
021	Scandium compounds
022	Titanium compounds
023	Vanadium compounds
024	Chromium compounds Chromium VI compounds
025	Manganese compounds

Family No Annex I to Directive 67/548/EEC	Families / Sub-families
026	Iron compounds
027	Cobalt compounds
028	Nickel compounds
029	Copper compounds
030	Zinc compounds Organometallic zinc derivatives
031	Gallium compounds
032	Germanium compounds
033	Arsenic compounds
034	Selenium compounds
035	Bromine compounds
036	Krypton compounds
037	Rubidium compounds
038	Strontium compounds
039	Yttrium compounds
040	Zirconium compounds
041	Niobium compounds
042	Molybdenum compounds
043	Technetium compounds
044	Ruthenium compounds
045	Rhodium compounds
046	Palladium compounds
047	Silver compounds

Family No Annex I to Directive 67/548/EEC	Families / Sub-families
048	Cadmium compounds
049	Indium compounds
050	Tin compounds Organometallic tin derivatives
051	Antimony compounds
052	Tellurium compounds
053	Iodine compounds
054	Xenon compounds
055	Caesium compounds
056	Barium compounds
057	Lanthanum compounds
058	Cerium compounds
059	Praseodymium compounds
060	Neodymium compounds
061	Promethium compounds
062	Samarium compounds
063	Europium compounds
064	Gandolinium compounds
065	Terbium compounds
066	Dysprosium compounds
067	Holmium compounds
068	Erbium compounds

Family No Annex I to Directive 67/548/EEC	Families / Sub-families
069	Thulium compounds
070	Ytterbium compounds
071	Lutetium compounds
072	Hafnium compounds
073	Tantalum compounds
074	Tungsten compounds
075	Rhenium compounds
076	Osmium compounds
077	Iridium compounds
078	Platinum compounds
079	Gold compounds
080	Mercury compounds Organometallic mercury derivatives
081	Thallium compounds
082	Lead compounds Organometallic lead derivatives
083	Bismuth compounds
084	Polonium compounds
085	Astate compounds
086	Radon compounds
087	Francium compounds
088	Radium compounds
089	Actinium compounds

Family No Annex I to Directive 67/548/EEC	Families / Sub-families
090	Thorium compounds
091	Protactinium compounds
092	Uranium compounds
093	Neptunium compounds
094	Plutonium compounds
095	Americium compounds
096	Curium compounds
097	Berkelium compounds
098	Californium compounds
099	Einsteinium compounds
100	Fermium compounds
101	Mendelevium compounds
102	Nobelium compounds
103	Lawrencium compounds
601	Hydrocarbons Aliphatic hydrocarbons Aromatic hydrocarbons Alicyclic hydrocarbons Polycyclic aromatic hydrocarbons (PAH)
602	Halogenated hydrocarbons (*) Halogenated aliphatic hydrocarbons (*) Halogenated aromatic hydrocarbons (*) Halogenated alicyclic hydrocarbons (*) (*) Specify according to the family corresponding to halogen.
603	Alcohols and derivatives Aliphatic alcohols Aromatic alcohols Alicyclic alcohols Alcanolamines Epoxy derivatives Ethers Glycolethers Glycols and polyols

Family No Annex I to Directive 67/548/EEC	Families / Sub-families
604	Phenols and derivatives Halogenated phenol derivatives (*) (*) Specify according to the family corresponding to halogen.
605	Aldehydes and derivatives Aliphatic aldehydes Aromatic aldehydes Alicyclic aldehydes Aliphatic acetals Aromatic acetals Alicyclic acetals
606	Ketones and derivatives Aliphatic ketones Aromatic ketones (*) Alicyclic ketones (*) Quinones included.
607	Organic acids and derivatives Aliphatic acids Halogenated aliphatic acids (*) Aromatic acids Halogenated aromatic acids (*) Alicyclic acids Halogenated alicyclic acids (*) Aliphatic acid anhydrides Halogenated aliphatic acid anhydrides (*) Aromatic acid anhydrides Halogenated aromatic acid anhydrides (*) Alicyclic acid anhydrides Halogenated alicyclic acid anhydrides (*) Salts of aliphatic acid Salts of halogenated aliphatic acid (*) Salts of aromatic acid Salts of halogenated aromatic acid (*) Salts of alicyclic acid Salts of halogenated alicyclic acid (*) Esters of aliphatic acid Esters of halogenated alicyclic acid (*) Esters of aromatic acid Esters of halogenated aromatic acid (*) Esters of alicyclic acid Esters of halogenated alicyclic acid (*) Esters of glycol ether Acrylates Methacrylates Lactones Acyl halogenides (*) Specify according to the family corresponding to halogen.
608	Nitriles and derivatives
609	Nitro compounds
610	Chlornitrated compounds

Family No Annex I to Directive 67/548/EEC	Families / Sub-families
611	Azoxy and azo compounds
612	Amine compounds Aliphatic amines and derivatives Alicyclic amines and derivatives Aromatic amines and derivatives Aniline and derivatives Benzidine and derivatives
613	Heterocyclic bases and derivatives Benzimidazole and derivatives Imidazol and derivatives Pyrethrinoids Quinoline and derivatives Triazine and derivatives Triazole and derivatives
614	Glycosides and alkaloids Alkaloid and derivatives Glycosides and derivatives
615	Cyanates and isocyanates Cyanates Isocyanates
616	Amides and derivatives Acetamide and derivatives Anilides
617	Organic peroxides
647	Enzymes
648	Complex coal derivatives Acid extract Alkaline extract Anthracene oil Anthracene oil extract residue Anthracene oil fraction Carbolic oil Carbolic oil extract residue Coal liquids, liquid solvent extraction Coal liquids, liquid solvent extraction solvents Coal oil Coal tar Coal tar extract Coal tar solids residue Coke (coal tar) low temperature, high temperature pitch Coke (coal tar), high temperature pitch Coke (coal tar), mixed coal high temperature pitch Crude benzole Crude phenols Crude tar bases Distillate bases Distillate phenols Distillates Distillates (coal), liquid solvent extraction, primary Distillates (coal), solvent extraction, hydrocracked Distillates (coal), solvent extraction, hydrocracked hydrogenated middle Distillates (coal), solvent extraction, hydrocracked middle

Family No Annex I to Directive 67/548/EEC	Families / Sub-families
648 *(cont'd)*	Extract residues (coal), low temperature coal tar alkaline Fresh oil Fuels, diesel, coal solvent extraction, hydrocracked, hydrogenated Fuels, jet aircraft, coal solvent extraction, hydrocracked, hydrogenated Gasoline, coal solvent extraction, hydrocracked naphtha Heat treatment products Heavy anthracene oil Heavy anthracene oil redistillate Light oil Light oil extract residues, high boiling Light oil extract residues, intermediate boiling Light oil extract residues, low boiling Light oil redistillate, high boiling Light oil redistillate, intermediate boiling Light oil redistillate, low boiling Methylnaphthalene oil Methylnaphthalene oil extract residue Naphtha (coal), solvent extraction, hydrocracked Naphthalene oil Naphthalene oil extract residue Naphthalene oil redistillate Pitch Pitch redistillate Pitch residue Pitch residue, heat treated Pitch residue, oxidised Pyrolysis products Redistillates Residues (coal), liquid solvent extractions Tar brown coal Tar brown coal, low temperature Tar oil, high boiling Tar oil, intermediate boiling Wash oil Wash oil extract residue Wash oil redistillate
649	Complex oil derivatives Crude oil Petroleum gas Low boiling point naphtha Low boiling point modified naphtha Low boiling point cat-cracked naphtha Low boiling point cat-reformed naphtha Low boiling point thermally cracked naphtha Low boiling point hydrogen treated naphtha Low boiling point naphtha — unspecified Straight-run kerosine Kerosine — unspecified Cracked gas oil Gas oil — unspecified Heavy fuel oil Grease Unrefined or mildly refined base oil Base oil — unspecified Distillate aromatic extract Distillate aromatic extract (treated) Foots oil Slack wax Petrolatum
650	Various substances Do not use this family. Instead, use the families or sub-families mentioned above.

4. **Practical application:**

After having conducted a search to see if the substance belongs to one or more families or sub-families on the list, the generic name can be established in the following way:

4.1. If the name of a family or sub-family is sufficient to characterise the chemical elements or important functional groups, this name will be chosen as the generic name.

Examples:

— 1,4 dihydroxybenzen
family 604: phenols and derivatives
generic name: phenol derivatives

— butanol
family 603: alcohols and derivatives
sub-family: aliphatic alcohols
generic name: aliphatic alcohol

— 2-Isopropoxyethanol
family 603: alcohols and derivatives
sub-family: glycolethers
generic name: glycolether

— methacrylate
family 607: organic acids and derivatives
sub-family: acrylates
generic name: acrylate

4.2. If the name of a family or sub-family is not sufficient to characterise the chemical elements of important functional groups, the generic name will be a combination of the corresponding different family or sub-family names:

Examples:

— chlorobenzene
family 602: halogenated hydrocarbons
sub-family: halogenated aromatic hydrocarbons
family 017: chlorine compounds
generic name: chlorinated aromatic hydrocarbon

— 2,3,6-trichlorophenylacetic acid
family 607: organic acids
sub-family: halogenated aromatic acids
family 017: chlorine compounds
generic name: chlorinated aromatic acid

— 1-chloro-1-nitropropane
family 610: chloronitrated derivatives
family 601: hydrocarbons
sub-family: aliphatic hydrocarbons
generic name: chlorinated aliphatic hydrocarbon

— tetrapropyl dithiopyrophosphate
family 015: phosphorus compounds
sub-family: phosphoric esters
family 016: sulphur compounds
generic name: thiophosphoric ester

NB: In the case of certain elements, notably metals, the name of the family or sub-family may be indicated by the words ‘organic’ or ‘inorganic’.

Examples:

— dimercury chloride
family 080: mercury compounds
generic name: inorganic mercury compound

— barium acetate
family 056: barium compounds
generic name: organic barium compound

— ethyl nitrite
family 007: nitrogen compounds
sub-family: nitrites
generic name: organic nitrite

— sodium hydrosulphite
family 016: sulphur compounds
generic name: inorganic sulphur compound

(The examples cited are substances taken from Annex I to Directive 67/548/EEC (19th adaptation) in respect of which requests for confidentiality may be submitted).

ANNEX VII

PREPARATIONS COVERED BY ARTICLE 12(2)

Preparations as specified by paragraph 9.3 of Annex VI to Directive 67/548/EEC.

ANNEX VIII

PART A

Directives repealed in accordance with Article 21

— Directive 78/631/EEC on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides)

— Directive 88/379/EEC on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations and its following adaptations to technical progress:

  — Directive 89/178/EEC

  — Directive 90/492/EEC

  — Directive 93/18/EEC

  — Directive 96/65/EC

— Directive 90/35/EEC defining in accordance with Article 6 of Directive 88/379/EEC the category of preparations the packaging of which must be fitted with child-resistant fastenings and/or carry a tactile warning of danger

— Directive 91/442/EEC on dangerous preparations the packaging of which must be fitted with child-resistant fastenings

PART B

Deadlines for transposition and for application in accordance with Article 22

Directive	Deadline for transposition	Deadline for application
78/631/EEC (OJ L 206, 29.7.1978, p. 13)	1 January 1981	1 January 1981
88/379/EEC (OJ L 187, 16.7.1988, p. 14)	7 June 1991	7 June 1991
89/178/EEC (OJ L 64, 8.3.1989, p. 18)	1 December 1990	1 June 1991
90/492/EEC (OJ L 275, 5.10.1990, p. 35)	1 June 1991	8 June 1991
93/18/EEC (OJ L 104, 29.4.1993, p. 46)	1 July 1994	1 July 1994
90/35/EEC (OJ L 19, 24.1.1990, p. 14)	1 August 1992	1 November 1992
91/442/EEC (OJ L 238, 27.8.1991, p. 25)	1 August 1992	1 November 1992
96/65/EC (OJ L 265, 18.10.1996, p. 15)	31 May 1998	31 May 1998

PART C

Special provisions for Austria, Finland and Sweden concerning the application of the following Directives in accordance with Article 21

1. Austria, Finland and Sweden do not transpose or apply Council Directive 78/631/EEC of 26 June 1978 on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides), as last amended by Council Directive 92/32/EEC of 30 April 1992.

2. Austria is to apply Council Directive 88/379/EEC of 7 June 1988 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations, as last amended by Directive 96/65/EC of 11 October 1996 under the following conditions:

   The following provisions of Directive 88/379/EEC will not apply to Austria

   (a) Article 13 in conjunction with Articles 3 and 7 with respect to preparations containing substances listed in Appendix 1;

   (b) Article 13 in conjunction with Article 7 with respect to labelling respecting the Austrian provisions on:

   — safety advice for waste disposal,

   — pictogram for waste disposal until two years after the entry into force of this Directive,

   — safety advice for countermeasures in case of accidents;

   (c) Article 13 in conjunction with Article 7(1)(c) concerning the chemical names of dangerous substances present in dangerous preparations, until two years after the entry into force of this Directive.

3. Sweden is to apply Council Directive 88/379/EEC of 7 June 1988 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations, as last amended by Directive 96/65/EC of 11 October 1996 under the following conditions:

   The following provisions of Directive 88/379/EEC will not apply to Sweden:

   (a) Article 13 in conjunction with Articles 3 and 7 with respect to preparations

   — containing substances listed in Appendix 2,

   — containing substances presenting neurotoxic effects and defatting effects on the skin not covered by criteria for classification of Annex VI to Directive 67/548/EEC, and by risk phrases of Annex III to Directive 67/548/EEC,

   — containing substances presenting acutely toxic effects not covered by criteria for classification of Annex VI to Directive 67/548/EEC, and by risk phrases of Annex III to Directive 67/548/EEC, until two years after the entry into force of this Directive,

   — which are not classified as dangerous according to the 'måttligt skadliga' (Swedish: 'moderately harmful') criteria of Directive 88/379/EEC.

   (b) Article 13 in conjunction with Articles 3 and 7 with respect to

   — the criteria for classification and labelling of preparations containing carcinogenic substances classified on the basis of criteria in point 4.2.1 of Annex VI to Directive 67/548/EEC,

   — labelling of preparations classified as carcinogenic, category 3, with a special R-phrase instead of R-phrase 40.

Appendix 1

Substances referred to in Annex VIII, Part C, paragraph 2 (Austria)

Name of the substance	Index number in Annex I to Directive 67/548/EEC
Linuron	006-021-00-1
Trichlorosilan	014-001-00-9
Phosphorus trichloride	015-007-00-4
Phosphorus pentachloride	015-008-00-X
Phosphorus oxychloride	015-009-00-5
Sodium polysulphides	016-010-00-3
Disulphur dichloride	016-012-00-4
Thionyl chloride	016-015-00-0
Calcium hypochlorite	017-012-00-7
Potassium hydroxide	019-002-00-8
2-Dimethylaminoethanol	603-047-00-0
2-Diethylaminoethanol	603-048-00-6
Diethanolamine	603-071-00-1
N-Methyl-2-ethanolamine	603-080-00-0
2-Ethylhexan-1,3-diol	603-087-00-9
Isophorone	606-012-00-8
6-Methyl-1,3-dithiolo(4,5-b)chinoxalin-2-one	606-036-00-9
Acetic anhydride	607-008-00-9
Methyl formate	607-014-00-1
Ethyl formate	607-015-00-7
Acrylic acid	607-061-00-8
Chloroacetyl chloride	607-080-00-1
Nitrofen	609-040-00-9
Quintozen; Pentachloronitrobenzol	609-043-00-5
Dichlofluanid	616-006-00-7
Cumene hydroperoxide	617-002-00-8
Monocrotophos	015-072-00-9
Edifenphos	015-121-00-4
Triazophos	015-140-00-8
Methanol	603-001-00-X
Trifenmorph; 4-Tritylmorpholin	613-052-00-X
Diuron	006-015-00-9
Fenbutanin oxide	050-017-00-2
1-Butanol, 2-Butanol, iso-Butanol	603-004-00-6

Appendix 2

Substances referred to in Annex VIII, Part C, paragraph 3 (Sweden)

Name of the substance	Index number in Annex I to Directive 67/548/EEC
Acetone	606-001-00-8
Butanone	606-002-00-3
Amyl formate	607-018-00-3
Ethyl acetate	607-022-00-5
n-Butylacetate	607-025-00-1
sec-Butylacetate	607-026-00-7
tert-Butylacetate	607-026-00-7
iso-Butylacetate	607-026-00-7
Butylformate	607-017-00-8
Cyclohexane	601-017-00-1
1,4-Dimethylcyclohexane	601-019-00-2
Diethyl ether	603-022-00-4
Ethyl methyl ether	603-020-00-3
Amyl acetate	607-130-00-2
Ethyl lactate	607-129-00-7
Amyl propionate	607-131-00-8
2,4-Dimethylpentan-3-one	606-028-00-5
Di-n-propylether	603-045-00-X
Di-n-propyl ketone	606-027-00-X
Ethyl propionate	607-028-00-8
Heptane	601-008-00-2
Hexane (mixture of isomers) containing less than 5 % n-hexane	601-007-00-7
Isopropyl acetate	607-024-00-6
Isopropyl alcohol	603-003-00-0
4-Methoxy-4-methylpentane-2-one	606-023-00-8
Methyl acetate	607-021-00-X
Methyl cyclohexane	601-018-00-7
5-Methylhexane-2-one	606-026-00-4
Methyllactate	607-092-00-7
4-Methylpentan-2-one	606-004-00-4
Methyl propionate	607-027-00-2
Octane	601-009-00-8
Pentane	601-006-00-1
Pentan-3-one	606-006-00-5
Propan-1-ol	603-003-00-0
Propyl acetate	607-024-00-6
Propyl formate	607-016-00-2
Propyl propionate	607-030-00-9

Name of the substance	Index number in Annex I to Directive 67/548/EEC
Sodium bisulphite = polysulphite	016-010-00-3
Toluene-2,4-diisocyanate	615-006-00-4
Toluene-2,6-diisocyanate	615-006-00-4
Cadmiumfluoride	048-006-00-2
1,2-Epoxy-3(tolyloxy)-propane	603-056-00-X
Diphenylmethane-2,2′-diisocyanate	615-005-00-9
Diphenylmethane-2,4′-diisocyanate	615-005-00-9
Diphenylmethane-4,4′-diisocyanate	615-005-00-9
Hydroquinone	604-005-00-4
Hydroxypropyl acrylate	607-108-00-2
Turpentine	650-002-00-6
Butyl methyl ketone (2-Hexanone)	606-030-00-6
Hexane	601-007-00-7
Vanadium pentoxide	023-001-00-8
Sodium nitrate	
Zinc oxide	

ANNEX IX

CORRELATION TABLE

This Directive	88/379/EEC
Article 1	Article 1
1.1	1.1
1.2	1.2
1.3	
1.4	
1.5	1.3
Article 2	Article 2
Article 3	Article 3.6
Article 4	Article 3.1
	Article 4
Article 5	Article 3.2
5.1	3.2
5.1, third indent	3.2, paragraph 3(b)
5.2—5.3	
5.4	
Article 6	Article 3.3
6.1	3.3, paragraphs (a) and (b)
6.2	
6.3	3.3, paragraphs 3 and 4
6.4	3.4
6.5	3.5, paragraphs 1 to 3
Article 7	
Article 8	Article 5
8.1	5.1
8.2	5.2
8.3	5.3
8.4	
Article 9	Article 6
9.1	6.1(a)
9.2	6.1(b)
9.3	6.2 and 6.3, second paragraph
Article 10	Article 7
10.1.1—1.2	
10.2	7.1
10.2.3.	7.1(c)
10.2.4.	7.1(d)
10.2.5.	7.4
Article 11	Article 8

This Directive	88/379/EEC
Article 12	Article 9
Article 13	
Article 14	Article 10
Article 15	Article 7
Article 16	Article 11
Article 17	Article 12
Article 18	Article 13
Article 19	Article 14
Article 20	Article 15
Article 21	
Article 22	Article 16
Article 23	Article 16(3)
Article 24	Article 17

CORRELATION TABLE

This Directive	88/379/EEC	90/35/EEC	91/442/EEC	93/18/EEC
Annex I.A	Article 3.2(2)			
Annex I.B				
Annex II.A. introduction (1—3)				Annex I introduction
Annex II.A. introduction (4)				
Annex II.A.1	Article 3.5(a)			
Annex II.A.1.1.1	Article 3.5(a)(i)			
Annex II.A.1.1.2	Article 3.5(a)(ii)			

This Directive	88/379/EEC	90/35/EEC	91/442/EEC	93/18/EEC
Annex II.A.1.2	Article 3.5(a)(iii)			
Annex II.A.2	Article 3.5(b)			
Annex II.A.2.1.1	Article 3.5(b)(i)			
Annex II.A.2.1.2	Article 3.5(b)(ii)			
Annex II.A.2.2	Article 3.5(b)(iii)			
Annex II.A.2.3	Article 3.5(b)(iv)			
Annex II.A.3	Article 3.5(c)			
Annex II.A.3.1.1	Article 3.5(c)(i)			
Annex II.A.3.1.2	Article 3.5(c)(ii)			
Annex II.A.3.2	Article 3.5(c)(iii)			
Annex II.A.3.3	Article 3.5(c)(iv)			
Annex II.A.4	Article 3.5(d)			
Annex II.A.4.1.1	Article 3.5(d)(i)			
Annex II.A.4.1.2	Article 3.5(d)(ii)			
Annex II.A.4.2.1	Article 3.5(e)(i)			
Annex II.A.4.2.2	Article 3.5(e)(ii)			
Annex II.A.5	Article 3.5(f)			
Annex II.A.5.1.1	Article 3.5(f)(i)			
Annex II.A.5.1.2	Article 3.5(f)(ii)			

This Directive	88/379/EEC	90/35/EEC	91/442/EEC	93/18/EEC
Annex II.A.5.2.1	Article 3.5(h)(i)			
Annex II.A.5.2.2	Article 3.5(h)(ii)			
Annex II.A.5.3.1	Article 3.5(g)(i)			
Annex II.A.5.3.2	Article 3.5(g)(ii)			
Annex II.A.5.4.1	Article 3.5(i)(i)			
Annex II.A.5.4.2	Article 3.5(i)(ii)			
Annex II.A.6				
Annex II.A.6.1	Article 3.5(g)(iii)			
Annex II.A.6.2	Article 3.5(c)(v)			
Annex II.A.7.1	Article 3.5(j)			Annex I.6
Annex II.A.7.2	Article 3.5(k)			
Annex II.A.8.1	Article 3.5(l), (m)			
Annex II.A.8.2	Article 3.5(n) Article 3.5(o), (p)			
Annex II.A.9.1—9.4				
Annex II.B. introduction				Annex I. introduction
Annex II.B.1				Annex I.1
Annex II.B.1.1				Annex I.1.1
Annex II.B.1.2				Annex I.1.2
Annex II.B.2				Annex I.2
Annex II.B.2.1				Annex I.2.1
Annex II.B.2.2				Annex I.2.2

This Directive	88/379/EEC	90/35/EEC	91/442/EEC	93/18/EEC
Annex II.B.3				Annex I.3
Annex II.B.3.1				Annex I.3.1
Annex II.B.3.2				Annex I.3.2
Annex II.B.4				Annex I.4
Annex II.B.4.1				Annex I.4.1
Annex II.B.4.2				Annex I.4.2
Annex II.B.5				Annex I.5
Annex II.B.5.1				Annex I.5.1
Annex II.B.5.2				Annex I.5.2
Annex II.B.6				Annex I.6
Annex II.B.6.1				Annex I.6.1
Annex II.B.6.2				Annex I.6.2
Annex III.A				
Annex III.B				
Annex III.C				
Annex IV.B		Articles 1 and 2		
Annex IV.A.1		Article 1(1)		
Annex IV.A.2			Article 2; Annex (a)	
Annex IV.A.3			Article 1; Annex (b)	
Annex V.A.1				Annex II.A.1
Annex V.A.2				Annex II.A.2
Annex V.A.3				Annex II.A.3
Annex V.A.4				Annex II.A.4
Annex V.B.1				Annex II.B.1
Annex V.B.2				Annex II.B.2

This Directive	88/379/EEC	90/35/EEC	91/442/EEC	93/18/EEC
Annex V.B.3				Annex II.B.3
Annex V.B.4				Annex II.B.4
Annex V.B.5				Annex II.B.5
Annex V.B.6				Annex II.B.6
Annex V.B.7	Article 3.2(3)(b)			
Annex V.B.8	Article 3.5(4)			
Annex V.C				
Annex VI				
Annex VII				
Annex VIII				
Annex IX				